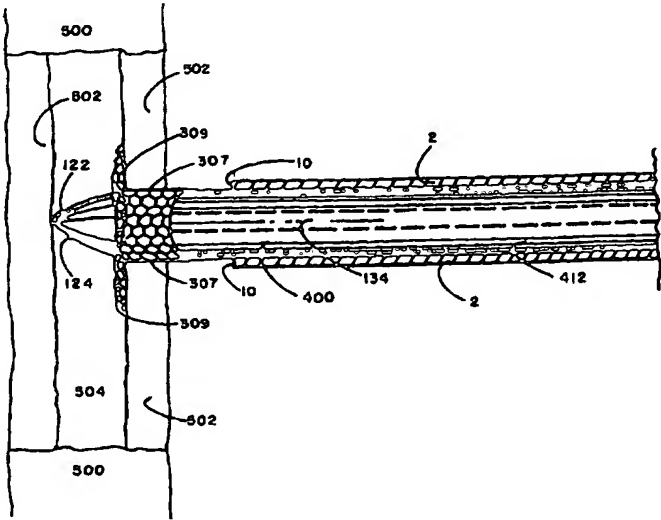


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(54) Title: CATHETER APPARATUS AND METHOD USING A SHAPE-MEMORY ALLOY CUFF FOR CREATING A BYPASS GRAFT <i>IN VIVO</i>			
			
(57) Abstract <p>The present invention provides a catheter (2), an introducer system (412), and a methodology for creating a bypass on demand between an unobstructed blood vessel (500) such as the aorta, and an obstructed blood vessel such as an obstructed coronary artery <i>in vivo</i> using a shaped memory alloy cuff (300) and a graft segment (400) in tandem as a shunt. The invention allows the placement and creation of single or multiple bypass grafts without use of a heart/lung machine, and without need for stopping the heart of the patient during the coronary artery bypass surgery.</p>			

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**CATHETER APPARATUS AND METHOD USING A SHAPE-MEMORY  
ALLOY CUFF FOR CREATING A BYPASS GRAFT IN-VIVO**

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**CROSS REFERENCE**

The present application is a Continuation-In-Part of United States Patent Application Serial No. 664,165 filed June 14, 1996, now pending.

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**FIELD OF THE INVENTION**

The present invention is concerned generally with minimally invasive vascular bypass surgery; and is directed to a catheterization methodology for creating a vascular bypass between an unobstructed artery or vein and an obstructed artery or vein in-vivo.

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**BACKGROUND OF THE INVENTION**

Coronary artery disease is the single leading cause of human mortality and is annually responsible for over 900,000 deaths in the United States alone. Additionally, over 3 million Americans suffer chest pain (angina pectoris) because of it. Typically, the coronary artery becomes narrowed over time by the build up of fat, cholesterol and blood clots. This narrowing of the artery is called arteriosclerosis; and this condition slows the blood flow to the heart muscle (myocardium) and leads to angina pectoris due to a lack of nutrients and adequate oxygen supply. Sometimes it can also completely stop the blood flow to the heart causing permanent damage to the myocardium, the so-called "heart attack."

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The conventional treatment procedures for coronary artery disease vary with the severity of the condition. If the coronary artery disease is mild, it is first treated with diet and exercise. If this first course of treatment is not effective, then the condition is treated with medications. However, even with medications, if chest pain persists (which is usually secondary to development of serious coronary artery disease), the condition is often treated with invasive procedures to improve blood flow to the heart. Currently, there are several types of invasive procedures: (1) Catheterization techniques by which cardiologists use balloon catheters, atherectomy devices or stents to reopen up the blockage of coronary arteries; or (2) Surgical

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bypass techniques by which surgeons surgically place a graft obtained from a section of artery or vein removed from other parts of the body to bypass the blockage.

Conventionally, before the invasive procedures are begun, coronary artery angiography is usually performed to evaluate the extent and severity of the coronary artery blockages. Cardiologists or radiologists thread a thin catheter through an artery in the leg or arm to engage the coronary arteries. X-ray dye (contrast medium) is then injected into the coronary artery through a portal in the catheter, which makes the coronary arteries visible under X-ray, so that the position and size of the blockages in the coronary arteries can be identified. Each year in U.S.A., more than one million individuals with angina pectoris or heart attack undergo coronary angiographies for evaluation of such coronary artery blockages. Once the blocked arteries are identified, the physician and surgeons then decide upon the best method to treat them.

One of the medically accepted ways to deal with coronary arterial blockage is percutaneous transluminal coronary angioplasty (PTCA). In this procedure, cardiologists thread a balloon catheter into the blocked coronary artery and stretch it by inflating the balloon against the arterial plaques causing vascular blockage. The PTCA procedure immediately improves blood flow in the coronary arteries, relieves angina pectoris, and prevents heart attacks. Approximately 400,000 patients undergo PTCA each year in the U.S. However, when the arterial blockages are severe or widespread, the angioplasty procedure may fail or cannot be performed. In these instances, coronary artery bypass graft (CABG) surgery is then typically performed. In such bypass surgery, surgeons typically harvest healthy blood vessels from another part of the body and use them as vascular grafts to bypass the blocked coronary arteries. Each vascular graft is surgically attached with one of its ends joined to the aorta and the other end joined to the coronary artery. Approximately 500,000 CABG operations are currently performed in the U.S. each year to relieve symptoms and improve survival from heart attack.

It is useful here to understand in depth what a coronary arterial bypass entails and demands both for the patient and for the cardiac surgeon. In a standard coronary bypass operation, the surgeon must first make a foot-long incision in the chest and split the breast bone of the patient. The operation requires the use of a heart-lung machine that keeps the blood circulating

while the heart is being stopped and the surgeon places and attaches the bypass grafts. To stop the heart, the coronary arteries also have to be perfused with a cold potassium solution (cardioplegia). In addition, the body temperature of the patient is lowered by cooling the blood as it circulates  
5 through the heart-lung machine in order to preserve the heart and other vital organs. Then, as the heart is stopped and a heart-lung machine pumps oxygenated blood through the patient's body, the surgeon makes a tiny opening into the front wall of the target coronary artery with a very fine knife (arteriotomy); takes a previously excised saphenous vein (a vein from a leg)  
10 or an internal mammary artery (an artery from the chest); and sews the previously excised blood vessel to the coronary artery.

The most common blood vessel harvested for use as a graft is the greater (long) saphenous vein, which is a long straight vein running from just inside the ankle bone to the groin. The greater saphenous vein provides a  
15 bypass conduit of the most desired size, shape, and length for use with coronary arteries. The other blood vessel frequently used as a bypass graft is the left or right internal mammary artery, which comes off the subclavian artery and runs alongside the undersurface of the breastbone (sternum). Typically, the internal mammary artery remains attached to the subclavian  
20 artery proximally (its upper part) but is freed up distally (its lower part); and it is then anastomosed to the coronary artery. However, the saphenous vein graft should be sewn not only to coronary artery but also to the aorta, since the excised vein is detached at both ends. Then, to create the anastomosis at the aorta, the ascending thoracic aorta is first partially clamped using a  
25 curved vascular clamp to occlude the proper segment of the ascending aorta; and a hole is then created through the front wall of the aorta to anchor the vein graft with sutures. The graft bypasses the blockage in the coronary artery and restores adequate blood flow to the heart. After completion of the grafting, the patient is taken off of the heart-lung machine and the patient's  
30 heart starts beating again. Most of the patients can leave the hospital in about 6 days after the CABG procedure.

It will be noted that coronary artery bypass surgery is considered a more definitive method for treating coronary arterial disease because all kinds of obstructions cannot be treated by angioplasty; and because a  
35 recurrence of blockages in the coronary arteries even after angioplasty is not unusual. Also coronary artery bypass surgery usually provides for a longer

patency of the grafts and the bypassed coronary arteries in comparison with the results of PTCA procedure. However, coronary artery bypass surgery is a far more complicated procedure, having need of a heart-lung machine and a stoppage of the heart. Also, it is clearly the more invasive procedure and is more expensive to perform than PTCA. Therefore, cardiac surgeons have recently developed an alternative to the standard bypass surgery, namely "minimally invasive bypass operation (MIBO) in order to reduce the risks and the cost associated with CABG surgery. Also, the MIBO is performed without use of a heart-lung machine or the stopping of the heart.

There are several ways that minimally invasive coronary bypass surgeries are being done today. Some versions are modeled after the video-assisted, fiber-optic techniques developed previously for gallbladder and other general surgeries. Other techniques have modified decades-old methods to sew arterial grafts onto beating hearts without using heart-lung machines. In the new and most popular version of the minimally invasive coronary bypass operation, surgeons use a thoracoscope, a fiber-optic device that is similar to a laparoscope. Initially, a three-inch incision is made to the left of the breast bone through which the surgeons operate. Three additional one-inch incisions then are made to insert a video camera, knife, surgical stapler, and other instruments. In the first stage of the operation, surgeons prepare the internal mammary artery, which courses vertically behind the rib cage, while watching on a video monitor. The internal mammary artery is freed up distally and is then sewn to the left anterior descending coronary artery. The internal mammary artery thus supplies blood to the coronary artery in place of blocked circulation of the heart. The wall of the chest formerly served by the mammary artery picks up blood from elsewhere via collateral blood circulations.

As a bypass graft, the left internal mammary artery (LIMA) offers a number of advantages to the coronary artery surgery including higher patency rate; and anatomically, histologically and geometrically provides a more comparable graft than the saphenous vein graft. LIMA is particularly useful as a graft to the coronary arteries such as the left anterior descending, diagonal branches, and ramus intermedius arteries (which are located on the surface of the heart relatively close to the left internal mammary artery).

However, there are several disadvantages associated with a CABG operation with a left internal mammary artery graft, which are as follows: (1) technically,

this artery is more tedious to take down; (2) sometimes the left internal mammary artery is inadequate in size and length; (3) the operation is suitable only for the five percent of candidates for coronary artery bypass because only a single left internal mammary artery is available as a graft; (4)

- 5 anatomically, the operation is limited mainly to the left anterior descending coronary artery because of its location and length; and (5) the majority of patients need more than single vessel bypass surgery.

In comparison, coronary arteries as small as 1 mm in diameter can be revascularized by vein grafting; and the saphenous vein is longer, larger, and  
10 more accessible than the left internal mammary artery. Equally important, although the greater or lesser saphenous veins of the leg are preferred, the cephalic or basilic veins in the arm are available as alternatives when the leg veins in the patient are unavailable or are unsuitable. For these reasons, the vein graft has today become the standard conduit for myocardial  
15 revascularization.

There remains, however, a long-standing and continuing need for a bypass technique which would allow surgeons to perform multiple bypass procedures using vein grafts as vascular shunts in a minimally invasive way; and, in particular, the need remains for a simpler method to place more than  
20 one vein graft proximally to the aorta and distally to the coronary artery without using a heart-lung machine and without stopping the heart. If such a technique were to be created, it would be recognized as a major advance in bypass surgery and be of substantial benefit and advantage for the patient suffering from coronary artery disease.

25

#### SUMMARY OF THE INVENTION

The present invention has multiple aspects. A first aspect is a catheter apparatus for creating a bypass on-demand between an unobstructed artery and an obstructed artery in-vivo using a graft segment as a conduit, said  
30 bypass catheter apparatus comprising:

a catheter suitable for introduction into and extension through the body in-vivo to a chosen site wherein an unobstructed artery is in anatomic proximity to an obstruction lying within another artery, said catheter being comprised of a hollow tube of fixed axial length having a discrete proximal  
35 end, a discrete distal end, and at least one internal lumen of predetermined diameter;

an obturator for on-demand introduction and passage through said catheter to a chosen site on the unobstructed artery in-vivo, said obturator comprising

5 (1) an expandable and contractible puncturing headpiece for puncture of and entry into the lumen of an unobstructed artery, said puncturing headpiece being expandable on-demand to a size greater than the diameter of said internal lumen of said catheter and being contractible on-demand to a size less than the diameter of said internal lumen of said catheter,

10 (2) a perforating end tip on said puncturing headpiece to facilitate the perforation of an arterial wall at the chosen site in-vivo

(3) an elongated shaft of fixed axial length integrated with said puncturing headpiece, said elongated shaft being configured for the carrying and transport of the graft conduit within said internal lumen of said catheter to the chosen vascular site on the unobstructed artery in-vivo,

15 (4) means for expanding and contracting said puncturing headpiece of said obturator on-demand; and

a thermoelastic cuff for positioning over said elongated shaft adjacent to said puncturing headpiece of said obturator together with the graft conduit, said cuff being comprised of a deformable thermoelastic shape-memory alloy, a portion of said thermoelastic cuff being substantially in a first shaped configuration at temperatures less than about 25-35°C while deforming into a memory-shaped second configuration at temperatures greater than about 25-35°C,

25 (i) wherein, prior to the perforation of the unobstructed artery in-vivo by said puncturing headpiece of said obturator, at least a portion of said thermoelastic cuff in a first shaped configuration has been engaged and joined to one end of the graft segment then carried by said elongated shaft of said obturator,

30 (ii) and wherein, after the perforation of the unobstructed artery in-vivo by said puncturing headpiece of said obturator, at least part of said engaged cuff is extended into the lumen of the unobstructed artery, is deformed in-situ into a memory-shaped second configuration, and said engaged cuff becomes attached via said deformation to the interior of the  
35 unobstructed artery,

(iii) and whereby said cuff engaged end of the graft segment become secured to and placed in blood flow communication with the unobstructed artery and serves as conduit means for bypassing an obstruction and restoring arterial blood flow from the unobstructed artery to the obstructed artery.

- 5 A second aspect of the invention defines a catheterization method for creating a bypass on-demand between an unobstructed artery and an obstructed artery in-vivo using a graft segment as a conduit, said bypass catheterization method comprising the steps of:
- 10 providing a catheter suitable for introduction into and extension through the body in-vivo to a chosen vascular site wherein an unobstructed artery is in anatomic proximity to an obstruction lying within another artery, said catheter being comprised of a hollow tube of fixed axial length having a discrete proximal end, a discrete distal end, and at least one internal lumen of
- 15 predetermined diameter,
- providing an obturator for on-demand introduction and passage through said catheter to a chosen site on the unobstructed artery in-vivo, said obturator comprising
- (1) an expandable and contractible puncturing headpiece for
- 20 puncture of and entry into the lumen of an unobstructed artery, said puncturing headpiece being expandable on-demand to a size greater than the diameter of said internal lumen of said catheter and also being contractible on-demand to a size less than the diameter of said internal lumen of said catheter,
- 25 (2) a perforating end tip on said puncturing headpiece to facilitate the perforation of an arterial wall at the chosen vascular site in-vivo
- (3) an elongated shaft of fixed axial length integrated with said puncturing headpiece, said elongated shaft being configured for the carrying and transport of a graft segment within said internal lumen of said
- 30 catheter to the chosen site on the unobstructed artery in-vivo,
- (4) means for expanding and contracting said puncturing headpiece of said obturator on-demand;
- placing a graft segment on the elongated shaft adjacent to said puncturing headpiece of said obturator;
- 35 positioning an undeformed thermoelastic cuff over said elongated shaft and one end of the graft segment lying adjacent to said puncturing headpiece

of said obturator such that at least a portion of said undeformed thermoelastic cuff engages and is joined to an end of the graft segment, said cuff being comprised of a deformable thermoelastic shape-memory alloy, a portion of said thermoelastic cuff being substantially in a first shaped configuration at  
5 temperatures less than about 25-35°C while deforming into a memory-shaped second configuration at temperatures greater than about 25-35°C;  
performing the unobstructed artery at the chosen site in-vivo using said puncturing headpiece of said obturator;  
extending at least part of said engaged thermoelastic cuff into the  
10 lumen of the unobstructed artery;  
deforming said extended thermoelastic cuff in-situ into the memory-shaped second configuration;  
(i) whereby said engaged cuff becomes attached via said deformation to the interior of the unobstructed artery,  
15 (ii) and whereby said cuff engaged end of the graft segment become secured to and placed in blood flow communication with the unobstructed artery; and  
joining the other end of the secured graft segment to the obstructed artery at a chosen site distal to the obstruction, said joined graft segment  
20 serving as a conduit means for bypassing the obstruction and restoring arterial blood flow from the unobstructed artery to the obstructed artery.

#### BRIEF DESCRIPTION OF THE FIGURES

The present invention may be more easily and completely understood  
25 when taken in conjunction with the accompanying drawing, in which:  
Fig. 1 is an overhead view of a conventionally known first catheter;  
Fig. 2 is an overhead view of a conventionally known second catheter;  
Figs. 3A and 3B are perspective and cross-sectional views of a single wall catheter tube of normal thickness;  
30 Figs. 4A and 4B are perspective and cross-sectional views of a single wall catheter tube of reduced thickness;  
Figs. 5A and 5B are perspective and cross-sectional views of a multiple-wall catheter tube of normal thickness;  
Figs. 6A and 6B are perspective and cross-sectional views of a  
35 multiple-wall catheter tube of reduced thickness;

Figs. 7A-7D are cross-sectional views of four different constructions of dual-lumen catheters;

Fig. 8 is an illustration of the distal end of a conventionally known guiding catheter;

5 Fig. 9 is a perspective view of a preferred first obturator;

Fig. 10 is a frontal view of the first obturator of Fig. 9;

Fig. 11 is a side view of the puncturing headpiece of the first obturator shown in Fig. 9;

10 Fig. 12 is a side view of the puncturing headpiece of Fig. 11 when in a contracted state;

Fig. 13 is a side view of the puncturing headpiece of Fig. 11 when in an expanded state;

15 Fig. 14 is an exposed view of a mechanical assembly used for expanding and contracting a puncturing headpiece on-demand in an obturator;

Fig. 15 is an exposed view of a hydraulic assembly for expanding and contracting a puncturing headpiece on-demand in an obturator;

Fig. 16 is a perspective view of a second obturator;

Fig. 17 is a frontal view of the second obturator of Fig. 16;

20 Fig. 18 is a perspective view of a third obturator;

Fig. 19 is a frontal view of the third obturator of Fig. 18;

Fig. 20 is a side view of an alternative fourth puncturing headpiece of an obturator;

25 Fig. 21 is a side view of an alternative fifth puncturing headpiece of an obturator;

Fig. 22 is a side view of an alternative sixth puncturing headpiece of an obturator;

Figs. 23A and 23B are views of a preferred first deformable cuff in the original undeformed state and the thermally deformed state;

30 Figs. 24A and 24B are overhead views of a preferred second deformable cuff in the original undeformed state and the thermally deformed state;

35 Figs. 25A and 25B are overhead views of an alternative third deformable cuff in the original undeformed state and the thermally deformed state;

Figs. 26A and 26B are overhead views of an alternative fourth deformable cuff in the original undeformed state; and the thermally deformed state;

Fig. 27 is a perspective view of a previously excised vascular segment position on the elongated shaft of the preferred first obturator of Fig. 9;

Fig. 28 is a perspective view of the preferred first deformable cuff of Fig. 23A in combination with the previously excised vascular segment shown in Fig. 27;

Fig. 29 is a partially exposed view of the introducer system as a whole;

Figs. 30A-30F are illustrations of the modified Seldinger technique conventionally used for percutaneous catheterization;

Fig. 31 is a partially exposed view of the introducer system in the correct position at the exterior wall of an unobstructed blood vessel in-vivo;

Fig. 32 is a partially exposed view of the introducer system penetrating the vascular wall of the unobstructed blood vessel in-vivo;

Fig. 33 is a partially exposed view of the introducer system within the internal lumen of the unobstructed blood vessel in-vivo;

Fig. 34 is a partially exposed view of the engaged cuff beginning thermal deformation in-situ while being extended into the internal lumen of the unobstructed blood vessel in-vivo;

Fig. 35 is a partially exposed view of the engaged cuff continuing thermal deformation within the internal lumen of the unobstructed blood vessel in-vivo;

Fig. 36 is a partially exposed view of the puncturing headpiece in the secondary contracted state after thermal deformation of the cuff in-situ within the internal lumen of the unobstructed blood vessel in-vivo;

Fig. 37 is a partially exposed view of the thermally deformed cuff and vascular segment secured fluid-tight to and in blood flow communication with the internal lumen of the unobstructed blood vessel in-vivo;

Fig. 38 is a partially exposed view of the bypass conduit grafted and secured to the unobstructed blood vessel in-vivo; and

Fig. 39 is a partially exposed view of the other open end of the bypass conduit anastomosed in the conventionally known manner to another obstructed blood vessel.

### DETAILED DESCRIPTION OF THE INVENTION

- The present invention is a catheter apparatus and catheterization technique for creating a single bypass or multiple bypasses on-demand
- 5 between an unobstructed blood vessel such as the aorta and an obstructed blood vessel such as an obstructed coronary artery in-vivo. The present invention utilizes either a synthetic prosthetic tubing (or channel section) or a previously excised vascular segment as a grafted conduit; and employs an introducer system using the catheter apparatus and a graft segment in
- 10 combination to create single or multiple shunts which overcome the obstruction and deliver arterial blood from a primary blood vessel, around the obstruction, into a secondary artery or vein in order to increase and/or maintain proper blood circulation in the living body. A number of substantial advantages and major benefits are therefore provided by the present
- 15 invention, some of which include the following:
1. The present invention provides the means for surgeons to perform multiple bypass grafts in a minimally invasive manner. The methodology permits the surgeon to utilize either synthetic prosthetic tubing (or channel sections) or previously excised veins as bypass conduits; and

20 allows the surgeon to place each of the bypass conduits from a primary unobstructed artery (such as the aorta) to a secondary obstructed artery (such as the obstructed coronary artery) without using a heart-lung machine and without need for stopping the heart during the surgery.

  2. The present invention simplifies the complexity of conventional

25 bypass surgery and makes the surgery less invasive. Moreover, the technique provides the ability to create multiple bypass conduits using a catheterization procedure which not only shortens the conventional operation time for surgery but also makes the bypass surgery safer and more cost effective.

  3. The present invention is suitable for creating a single bypass

30 graft or multiple bypass grafts in any medical situation, condition, or pathology in which there is a need for increased blood flow to a specific blood vessel or vascular area or body region. The cause or source of the medical problem may be an obstruction in a blood vessel; or a narrowing or thickening

35 of a blood vessel wall; or a diminution or narrowing of a vascular section in a particular blood vessel. Each of these medical conditions has its particular

cause, origin, or source; and each of these pathologies, though different in origin, causes a similar effect overall -- a loss of blood flow and blood pressure within the blood vessel. Accordingly, the present invention is deemed useful and desirable to overcome any of these particular medical conditions and instances where there is a demonstrated need for increased blood pressure and blood volume flow within a particular blood vessel in the body.

4. The present apparatus and methodology can be employed to create a bypass conduit between any two blood vessels. In many instances, the bypass conduit is made between a primary unobstructed artery and a secondary obstructed artery, a typical example being a bypass between the ascending aorta and an obstructed coronary artery. However, a bypass shunt may also be created between any two veins (such as between the portal vein and the inferior vena cava); or between an artery and a vein (such as between the superior vena cava and a pulmonary artery). Equally important, although the primary focus of the present invention is the thoracic cavity and the recognized need for bypass conduits among the blood vessels found therein, the present apparatus and methodology may be employed anywhere in the human body where there is a need for increased vascularization or revascularization of the local region. The sole limitation, therefore, is a means of access for the catheter apparatus, the introducer system, and the methodology to be performed by the skilled surgeon and interventional radiologist.

In order to provide a complete and comprehensive understanding of the present invention, the detailed description is given as a series of individual sections presented seriatim. These will include the following: the component parts of the catheter apparatus; the synthetic prosthetic channel section or excised blood vessel segment to be used as a bypass conduit; the introducer system utilizing the catheter apparatus and bypass conduit in combination; general techniques of catheter routing and surgical introduction; the methodology and individual manipulations for creating a bypass graft; and an illustrative summary of the preferred surgical procedures using the catheter apparatus, introducer system, and methodology. Each of these will be described and characterized individually.

## **I. The Component Parts Of The Catheter Apparatus**

Three essential component parts comprise the catheter apparatus needed to create a bypass in-vivo. These are: a flexible guiding catheter; an  
5 obturator having a puncturing headpiece; and a deformable thermoelastic cuff for engaging and securing a synthetic prosthesis or a previously excised vascular segment as a bypass conduit to an unobstructed major blood vessel (such as the aorta). Each of these component parts will be described in detail individually.

10

### **A. The Flexible Guiding Catheter**

The in-vivo bypass catheterization method comprising the present invention requires that a controlling or guiding flexible catheter be employed as an essential part of the apparatus and manipulations. This controlling or  
15 guiding flexible catheter has at least one tubular wall of fixed axial length; has at least one proximal end for entry; has at least one distal end for egress; and has at least one internal lumen of a volume sufficient to allow for on-demand controlled passage therethrough of a prepared obturator carrying a deformable thermoelastic cuff and a bypass conduit.

20 Catheters, particularly surgical catheters, are conventionally known and used; and a wide range and variety of guiding catheters are available which are extremely diverse in shape, design, and specific features. All of the essential requirements of a guiding flexible catheter exist as conventional knowledge and information in the relevant technical field; and all of the  
25 information regarding catheter design and provided in summary form hereinafter is publicly known, widely disseminated, and published in a variety of authoritative texts. The reader is therefore presumed to be both familiar with and have an in-depth knowledge and understanding of the conventional diagnostic and therapeutic uses of catheters and catheterization techniques.  
30 Merely representative of the diversity of publications publicly available are the following, each of which is expressly incorporated by reference herein: Diagnostic and Therapeutic Cardiac Catheterization, second edition (Pepine, Hill, and Lambert, editors) Williams & Wilkins, 1994 and the references cited therein; A Practical Guide To Cardiac Pacing, fourth edition (Moses et. al.,  
35 editors) Little, Brown, and Company, 1995 and the references cited therein;

Abrams Angiography, third edition (H. L. Abrams, editor), Little, Brown, and Company, 1983.

5 A number of specific types of controlling or guiding catheters are known today; but for purposes of practicing the present invention, a number of newly designed or specifically designed catheters of varying lengths and sizes suitable for bypass use are expected and intended to be developed and manufactured subsequently. Equally important, minor modifications of the presently existing general categories of catheters are equally appropriate and are expected to be found suitable for use when practicing the present  
10 invention. Accordingly, a summary review of the conventionally known catheter types as well as a overall description of general catheter design and the principles of catheter construction are presented herein.

**Catheter construction and design:**

15 Presently known specific types of catheters include the following: central venous catheters which are relatively short (usually 20-60 centimeters) in length and are designed for insertion into the internal jugular or subclavian vein; right heart catheters such as the Cournard catheter designed specifically for right heart catheterization; transseptal catheters  
20 developed specifically for crossing from right to left atrium through the interarterial septum at the fossa ovalis; angiographic catheters which are varied in shape and are frequently used today in the femoral and brachial approach for cardiac catheterization and angiography in any of the major vessels; coronary angiographic catheters which include the different series of grouping including Sones, Judkins, Amplatz, multipurpose, and bypass graft  
25 catheters; as well as many others developed for specific purposes and medical conditions.

Merely representative of guiding and controlling flexible catheters, generally presented herein without regard to their specific past usages or  
30 intended applications, are those illustrated by Figs. 1 and 2 respectively. As exemplified by Fig 1, a catheter 2 is seen having a tubular wall of fixed axial length; having two proximal portals 4 and 6 which together generate the proximal end 8 for entry into the interior of the catheter; a single distal portal 10 and the distal end 12 of the catheter; and an internal lumen 14 (which is  
35 not visible in the illustration).

Another variation commonly known is illustrated by Fig. 2 which shows a controlling flexible catheter 20 having a tubular wall of fixed axial length; three proximal portals 21, 22 and 23 respectively which collectively form the proximal end 24 for entry into the internal volume of the catheter; and a single  
5 distal portal 25 which designates the distal end 26 or tip of the catheter. It will be appreciated and understood that Figs. 1 and 2 are presented merely to show the overall general construction and relationship of parts present in each flexible controlling catheter suitable for use with the present methodology.

10 In accordance with established principles of conventional catheter construction, the axial length of the catheter may be composed of one or several layers in combination. In most multilayered constructions, one hollow tube is stretched over another to form a bond; and the components of the individual layers determine the overall characteristics for the catheter as a  
15 unitary construction. Most multilayered catheters comprise an inner tube of teflon, over which is another layer of nylon, woven Dacron, or stainless steel braiding. A tube of polyethylene or polyurethane is then heated and extruded over the two inner layers to form a bond as the third external layer. Other catheter constructions may consist of a polyurethane inner core, covered by a  
20 layer of stainless steel braiding, and a third external jacket layer formed of polyurethane.

Several examples of basic catheter construction and design are illustrated by Figs. 3-6 respectively. Figs. 3A and 3B are perspective and cross-sectional views of a single tubular wall considered the standard  
25 minimum construction for a catheter. Figs. 4A and 4B are perspective and cross-sectional views of a thin-walled design for a single layer extruded catheter. In comparison, Figs. 5A and 5B are perspective and cross-sectional views of a standard multilayered catheter construction having a braided stainless steel midlayer in its construction. Finally, Figs. 6A and 6B  
30 are perspective and cross-sectional views of a thin-walled design for a multilayered catheter with a braided stainless steel middle layer.

Catheters are generally sized by external and internal diameter and length. The internal specified either by diameter (in thousandths of an inch or millimeters or French). Many newer thin-walled catheter designs provide a  
35 much larger internal lumen volume to external diameter ratio than has been previously achieved; and this has resulted in catheters which can

accommodate much more volume and allow the passage of much larger sized articles through the internal lumen. External diameter is typically expressed in French sizes which are obtained by multiplying the actual diameter of the catheter in millimeters by a factor of 3.0. Conversely, by traditional habit, the size of any catheter in millimeters may be calculated by dividing its French size by a factor of 3.0. French sizes from 5-8 are currently used for diagnostic angiography. For purposes of practicing the present invention, it is also desirable that French sizes ranging from 4-16 respectively be employed unless other specific size requirements are indicated by the particular application or circumstances. In addition, because of the variation between standard, thin-walled, and super high-flow catheter construction designs, a range and variety of external and internal lumen diameter sizes exist. To demonstrate the conventional practice, the data of Table 1 is provided.

**Dual-lumen catheters:**

A number of different dual-lumen catheters are known today which differ in the size and spatial relationship between their individual lumens. This is illustrated by Figs. 7A-7D respectively which show different dual-lumen constructions for four catheters having similar or identical overall diameter (French) size.

As shown therein, Fig. 7A shows a dual-lumen catheter 30 wherein a first external tubular wall 32 provides an outer lumen volume 34 into which a second internal tubular wall 36 has been co-axially positioned to provide an inner lumen volume 38. Clearly, the construction of catheter 30 is a co-axial design of multiple tubular walls spaced apart and co-axially spaced but separate internal lumens of differing individual volumes.

In comparison, Fig. 7B shows a second kind of construction and design by dual-lumen catheter 40 having a single external tubular wall 42; and an centrally disposed inner septum 44 which divides the interior tubular space into two approximately equally lumen volumes 46 and 48 respectively. Thus, in this construction, the diameter, length, and volume of internal lumen 46 is effectively identical to the diameter, length and volume of internal lumen 48; and both of these exist and are contained within a single, commonly-shared, tubular wall.

A third kind of construction is illustrated by Fig. 7C and shows an alternative kind of construction and design to Fig. 15B. As seen in Fig. 7C, dual-lumen catheter 50 has a single external tubular wall 52; and contains an asymmetrically positioned internal divider 54 which divides the interior tubular space into two unequal and different lumen volumes 56 and 58 respectively. Thus, in this alternative construction, the discrete volume of internal lumen 56 is markedly smaller than the volume of the adjacently positioned internal lumen 58; and yet both of these internal lumens 56 and 58 exist in, are adjacently positioned, and are both contained within a commonly-shared single tubular wall.

A fourth construction and design for a dual-lumen catheter is presented by Fig. 7D which shows a catheter 60 having a single external tubular wall 62 of relatively large size and thickness. Within the material substance 68 of the tubular wall 60 are two discrete bore holes 64 and 66 of differing diameters which serve as two internal lumens of unequal volume. Internal lumen 64 is clearly the smaller while internal lumen 66 is far greater

in spatial volume. Yet each internal lumen volume 64 and 66 is adjacent to the other, lies in parallel, and follows the other over the axial length of the catheter.

5 In general, the tubular body of the catheter is generally straight over most of its length and may have different bends or curves towards the distal end or tip. A representative illustration of the distal end of a catheter is illustrated by Fig. 8. The individual bends in the catheter are traditionally called "curves"; and the terms "primary, secondary, etc.," are applied to each additional curve further away from the distal tip as is illustrated by Fig. 8.  
10 Accordingly, the primary curve 100 is followed by the secondary curve 102 for the catheter body 104 generally. The catheter tip 106 is its most distal segment. In addition, the catheter distal tip 106 may have any combination of a single end hole 110 or an open distal end 108 and any number of side holes 110, 112 which function as portals for fluids and gases exiting the distal  
15 end of the catheter.

Conventional practice permits a number of different distal ends or tips which vary in design and appearance. Merely representative of these permitted and conventional variances in distal end design for catheters generally are the distal ends of ventricular catheters which include: a "pigtail"  
20 design and construction which has a curled-tip format and multiple side holes; the Lehman ventricular catheter end which provides a number of side holes in different places along the distal end; and the Gensini design which provides multiple side holes at varying angles. Accordingly, for purposes of practicing the present repair methodology, any construction of the catheter  
25 distal end whether having one or more curves, or none; and whether or not there is more than one central portal for exiting the lumen or multiple side holes, are all considered conventional variations in construction design. Any and all of these distal tip designs and constructions are therefore deemed to be encompassed completely and to lie within the general catheter scope of  
30 construction suitable for use with the present invention.

#### B. The Obturator

The second requisite component part of the catheter apparatus is the obturator. Each embodiment of an obturator is comprised of at least three  
35 parts, and preferably comprises four component parts. The minimal requisite three elements include a puncturing headpiece; a perforating end tip on the

headpiece; an elongated shaft integral with the puncturing headpiece. The fourth highly desirable component is the means for expanding and contracting the size of the puncturing headpiece on-demand. Various embodiments representative of each of these structural components are individually illustrated within Figs. 9-15 respectively.

One general embodiment of an obturator is illustrated by Figs. 9-10. As seen therein, the obturator 120 comprises a puncturing headpiece 122 which is substantially bullet-shaped (frusto-conical) in configuration, and comprises an outer shell 124 and a base plate 126. The outer shell 124 has determinable surface dimensions and an overall girth which can be either fixed or varied in size. At the distal end 128 of the puncturing headpiece 122 is a perforating end tip 130 which appears as a cross-shaped (or cone-shaped) cutting edge for the headpiece 122. As shown by Fig. 10, the perforating end tip 130 does not extend over the entire surface area of the outer shell 124; instead, the perforating end tip 130 is limited in size and orientation to the distal end 128. The perforating end tip 130 serves as the sharp cutting edge for the obturator 120 as a whole.

Integral with the puncturing headpiece 122 is an elongated shaft 134 whose overall axial length may be varied to accommodate the surgeon and the particular medical circumstances of usage. The distal end 136 of the shaft is integrated with the puncturing headpiece 122 and can provide access to the interior volume of the headpiece bounded by the outer shell 124 and the base plate 126. The proximal end 138 of the elongated shaft 134 is intended to be held by the surgeon performing the vascular bypass surgery. Accordingly, the axial length of the elongated shaft 134 will vary and accommodate the surgeon; and thus vary from a few inches to a few feet in length. The function of the elongated shaft 134 is for the carrying and transport of a bypass conduit to the chosen site on the unobstructed or primary blood vessel in-vivo. The elongated shaft 134 acts to support, maintain and convey the conduit within the lumen of the catheter in a manner such that the conduit can be used as a bypass graft.

#### **The fixed size embodiments of the obturator**

The minimalist format for the obturator does not provide any means nor mechanism to alter the surface dimensions or configuration of the puncturing headpiece integrated with the elongated shaft. Thus, the initial

dimensions and girth for the puncturing headpiece 122 shown by Figs. 9 and 10 respectively will remain constant and fixed; and neither the size, shape, aspect ratios, nor overall geometry will be changed or modified during the intended in-vivo use for the obturator embodiment. The fixed size  
5 embodiment, however, is a less preferred format for clinical applications; and this minimalist format may cause more procedural difficulty and inconvenience for the surgeon than the preferred variable-size embodiments of the obturator.

10 **The variable-size embodiments of the obturator**

A highly desirable and preferred component feature of the puncturing headpiece and the obturator as a whole is that means exist for expanding and contracting the puncturing headpiece on-demand. The effect of this fourth feature and capability for the obturator is illustrated by Figs. 11-13  
15 respectively. As seen within Fig. 11, the puncturing headpiece 122 appears in its initial size identical to that shown by Figs. 9 and 10. The outer shell 124 is substantially cone-shaped in configuration, has an initial internal volume, and has a girth dimension  $d$  equal to the initial diameter of the base plate 126. The internal volume of the puncturing headpiece, as determined by the  
20 dimensions of the outer shell 124 and the base plate 126, provides an initial internal volume of determinable quantity.

When the mechanism for contracting the puncturing headpiece is activated, the consequence is illustrated by Fig. 12 in which the dimensions of the outer shell 124 have been diminished and the girth of the headpiece  
25 has been reduced as shown by the reduced diameter  $d'$  of the base plate 126. Note also, that as the puncturing headpiece 122 becomes contracted in overall volume and dimensions, the configuration of the puncturing headpiece 122 has consequentially become altered and now appears to be spear-like in configuration. Similarly, the overall angular disposition of the perforating end  
30 tip 130 serving as the cutting edge will also be slightly altered in overall appearance as a consequence of contracting the puncturing headpiece 122.

Alternatively, when the puncturing headpiece 122 is expanded, the overall result is shown by Fig. 13. As seen therein, the outer shell 124 has been expanded in overall dimensions and volume; and the girth of the  
35 headpiece has been expanded and can be determined by the diameter  $d''$  of the expanded base plate 126. Note that the overall appearance of the

puncturing headpiece has been altered as a consequence of its expansion and now appears to be elliptical in shape overall. Similarly, the perforating end tip 130 has similarly been altered in appearance and has angularly expanded somewhat to conform with the expanded dimensions and angularity of the outer shell 124.

It will be recognized and appreciated also that throughout the changes in appearance, internal volume (designated as V, V' and V'') and overall size for the contracted or expanded puncturing headpiece 122 (as shown via Figs. 11, 12, and 13 respectively), the dimensions and overall configuration of the elongated shaft 134 have not been altered meaningfully or significantly. Although this is not an absolute requirement in each and every embodiment of an obturator, it is preferred that the elongated shaft 134, particularly at the integrated distal end 136, remain constant in size and volume as much as possible and be unaffected subsequent to the on-demand expansion or contraction of the puncturing headpiece 122. This preference and feature will maintain the integrity of the synthetic prosthesis or the excised vascular segment intended to be carried and transported by the elongated shaft during the bypass grafting procedure. Thus, to avoid or minimize any physical damage to the graft material, it is desirable that the elongated shaft be maintained in appearance, configuration and dimensions without change whenever possible.

#### **Means for contracting or expanding the puncturing headpiece**

A feature and component of each preferred obturator is the existence and availability of specific means for expanding and contracting the puncturing headpiece on-demand. A number of different mechanisms and means for expanding and contracting the puncturing headpiece of the obturator are conventionally known and easily employed. Merely to demonstrate some different and conventionally known mechanisms, attention is directed to the means illustrated by Figs. 14 and 15 respectively.

The means for expanding and contracting the puncturing headpiece on-demand illustrated by Fig. 14 constitute a mechanical approach and design mechanism which is carried within the internal volume of the puncturing headpiece 122 and the integrated elongated shaft 134. As seen therein, a central rod 150 extends through the hollow interior of the elongated shaft 134 and extends into the internal volume defined by the outer shell 124

and the base plate 126 of the puncturing headpiece 122. Within the internal volume of the outer shell 124, a plurality of rotatable ribs 152 are joined to the central rod 150 at the distal end to form a central pivot point 154. Each rotatable rib 152 is mobile and pivotable around the central point 154 and forms an umbrella-like scaffolding structure which can be expanded outwardly or collapsed inwardly at will. Mounted on the central rod 150 is an expansion wheel 156. This expansion wheel 156 is centrally mounted on the rod 150; is moveable over the axial length of the central rod 150; and is controlled in the direction of axial movement (distally and proximally). The expansion wheel 156 comprises a center hub 158 and a plurality of hub supports 160, both of which maintain the expansion wheel in proper position as it engages the plurality of rotatable ribs 152. Joined to the central hub 158 of the expansion wheel 156 are linear movement members 162 which are positioned within the interior volume of the elongated shaft 134 and have a length sufficient to reach to the proximal end 138 of the elongated shaft 134 for control by the surgeon or invasive radiologist. The linear movement members 162 engage the center hub 158 of the expansion wheel 156; and extend or withdraw the expansion wheel closer to or away from the perforating end tip 130 of the puncturing headpiece 122. When the expansion wheel is engaged and pushed forward, expansion wheel engages the rotatable ribs 152 and expands the rotatable ribs outwardly thereby increasing the overall girth of the puncturing headpiece as a unit. Alternatively, when the linear movement members 162 are withdrawn, the expansion wheel recedes towards the proximal end and the engaged rotatable ribs 152 collapse inwardly within the volume of the outer shell 124. The consequence of this movement is a contraction of the puncturing headpiece 122 as a unit. It will be recognized and appreciated that this mechanical approach for expanding and contracting the puncturing headpiece is completely conventional in design and operation; and accordingly, any conventional refinement of these basic component parts is considered to be a variation within the scope of this mechanical system.

As a representated alternative, hydraulic means for expanding and contracting the puncturing headpiece of the obturator on demand is also provided. In this system, as shown by Fig. 15, the internal volume of the puncturing headpiece 122 and the integrated elongated shaft 134 includes an elastic sack 180 comprised of a fluid containing elastic bubble 182 and a fluid delivering elastic conduit 184. The outer shell 124 and base plate 126 of the

puncturing headpiece 122 are as previously shown; and the headpiece 122 is integrated with the elongated shaft 134 as previously described herein.

Within the internal volume of the puncturing headpiece 122, is a fluid containing elastic bubble 182 which is in fluid communication with the elastic conduit 184 carried within the internal volume of the elongated shaft 134. The elastic sack 180 is formed of elastomeric material (such as rubber, elastic plastic, and the like) and is fluid-tight along its seams. The elastic sack 180 contains any liquid which is compatible with the material of the elastic sack; and it is the intrinsic nature of the material forming the elastic sack 180 that the material exerts a compression force or pressure upon the fluid contained within the elastic sack itself. In this way a hydraulic system for expanding and contracting the puncturing headpiece of the obturator is created.

As fluid is introduced through the elastic conduit 180 by the surgeon or invasive radiologist, that fluid is conveyed and delivered into the elastic bubble 182 positioned within the puncturing headpiece 122. The elasticity of the bubble 182 exerts a mild compression force and pressure against the quantity of fluid contained within the bubble interior volume; accordingly, the greater the quantity of fluid within the elastic bubble 182, the larger in overall volume the elastic bubble becomes. Thus, as more fluid is delivered through the conduit 184 into the elastic bubble 182, the larger in overall volume the elastic bubble becomes; and as the volume of the elastic bubble expands, the overall configuration and internal volume of the piercing headpiece 122 also enlarges. In this manner, by carefully controlling the amount of fluid conveyed through the conduit 184 into the elastic bubble, the overall size and configuration of the piercing headpiece 122 can be controllably expanded. Subsequently, to reduce the overall size and configuration of the puncturing headpiece 122, a quantity of fluid is permitted to be released from the elastic conduit 184 at the proximal end by the surgeon or radiologist. Because the material is elastic and exerts a compression force against the quantity of fluid present within the bubble at any given moment in time, the release of fluid through the elastic conduit will cause a reduction in overall size for the elastic bubble 182; and as the overall volume of the elastic bubble is reduced in size, the puncturing headpiece will consequently be contracted and reduced in configuration and overall volume as well. It will be noted and appreciated also that this hydraulic mechanism for expanding and contracting the

puncturing headpiece on demand is a conventionally known fluid system and technique; and many conventionally known variations and changes in hydraulic design and fluid control systems are presently known and commonly available for use. Accordingly, all hydraulic systems are  
5 envisioned as suitable for use as one means for expanding and contracting the puncturing headpiece of the obturator on-demand.

#### **Alternative obturator structures**

A number of different physical embodiments for the obturator are also  
10 envisioned and intended for use. Some examples, which are merely illustrative of the range and variety of physical formats and which serve to merely illustrate the range and degree of difference available for the various puncturing headpieces of an obturator, are illustrated by Figs. 16-22 respectively. It will be recognized and understood, however, that these  
15 alternative embodiments are merely representative of obturators and puncturing headpieces generally and do not signify any limitation or restriction on their structural construction or design.

The embodiment illustrated by Figs. 16 and 17 respectively shows a puncturing headpiece 200 which is substantially cone-shaped in overall  
20 appearance and comprises an outer shell 202 and a base plate 206. The distal end 208 of the puncturing headpiece 200 has a perforating end tip 210 which is also substantially cone-shaped in configuration and appearance and covers only a small surface area of the outer shell 202. Integral with the puncturing headpiece is the elongated shaft 134 as described previously  
25 herein; and means for expanding and contracting the puncturing headpiece 200 on-demand are included within the obturator as a integrated unit.

Another embodiment for the puncturing headpiece is illustrated by Figs. 18 and 19 respectively. As shown therein, the puncturing headpiece 220 comprises the outer shell 222 and the base plate 224 integral with the  
30 elongated shaft 134. A particular feature of this embodiment, however, is the distal end 226 seen most clearly within Fig. 19 as providing a perforating end tip 230 which is substantially star-shaped and extends over the surface area of the outer shell 222. The result is to provide a series of grooves 228 alternating with sharp cutting edges 232 over the surface of the outer shell  
35 222. This embodiment for the puncturing headpiece 220 provides a much

greater area for cutting and perforation as a specific feature of the obturator design.

To demonstrate further the variety and degree of differences envisioned and intended when constructing a puncturing headpiece, the structural constructions exemplified by Figs. 20-22 respectively are provided. As illustrated by Fig. 20, the puncturing headpiece 250 includes a buttressing region 254 as a part of the outer shell 252. The buttressing region 254 is a reinforced region for engaging materials placed in contact with the outer shell when the puncturing headpiece is expanded. The puncturing headpiece 250 includes a base plate 256 and is integrated with the elongated shaft 134 (described previously herein).

In comparison, the puncturing headpiece 260 exemplified by Fig. 21 is a sharply tapered and contoured embodiment in which the outer shell 262 includes a spiral girth zone 264 suitable for deforming elastic materials. The base plate 266 conforms to and is integrated with the spiral zone 264.

Another alternative embodiment of the puncturing headpiece is illustrated by Fig. 22. In this embodiment, the puncturing headpiece 280 comprises an outer shell 282 and a concave-shaped or scalloped zone 284 which is joined to and integrated with the base plate 286. The concave-shaped configuration of the zone 284 is intended to aid the puncturing headpiece as it is expanded and contracted on-demand.

### C. The Deformable Thermoelastic Cuff

An essential component part of the catheter apparatus and method for creating a bypass graft is the presence and use of a deformable thermoelastic cuff comprised of a shape-memory alloy composition.

The shape-memory metal alloy compositions to be used with the present invention constitute conventionally known blends and formulated metallic mixtures of nickel and titanium which undergo a phase transition – that is, a molecular rearrangement of atoms, molecules or ions within a lattice structure – due to a temperature change. The unique capability of shape-memory alloys is that these alloys change shape or configuration as a direct consequence of a change in temperature; and the alloy composition "remembers" its earlier and specifically prepared shape because the phase change affects its structure on the atomic level only, without disturbing the arrangement of the molecules which would otherwise be irreversible.

When these shape-memory alloys are intentionally superheated far above their transition temperature (either electrically or by external heat), a stretched temperature transformed alloy format results which contracts and exerts considerable force; and the temperature transformed alloy composition will become memory-shaped in a fixed specific configuration. Afterwards, when cooled to below its transition temperature, the alloy composition can then be bent and shaped into other configurations while retaining the fixed "memory" of the particular shape in the earlier superheated condition. Thus, these shape-memory alloy compositions are recognized as being both deformable and thermoelastic, as well as being able to revert to a prepared memory-shaped configuration as a consequence of being warmed to a temperature above its individual transition temperature.

#### **Alloy formulations**

At least twenty different formulations of these alloys are conventionally known to exhibit the shape-memory effect and property, all of these comprising different mixtures of nickel and titanium in varying percentage ratios [Design News, June 21, 1993 issue, pages 73-76]. These metal alloys are today utilized in the manufacture of differing products. For example, a range of different shape-memory alloy wires are commercially available in diameters from 0.001-0.010 inches (Dynalloy Inc., Irvine, California). In addition, surgical anchors having superelastic properties and formed by two or more arcs of wire strands (which can withstand strains exceeding 10%) have been developed [Mitek Surgical Products, Inc., Norwood, Massachusetts]. Also, blood clot filters formed of shape-memory alloy wires are commercially sold for implantation in large blood vessels such as the vena cava [Nitinol Medical Technologies, Inc., Boston, Massachusetts]. While these commercially available products illustrate the use of one or more shape-memory alloy formulations by the manufacture of their particular articles, a more general listing of conventionally known properties and characteristics for shape-memory alloy compositions is provided by Table 2 below.

Table 2:

**Conventionally Known Properties Of**  
**Shape-Memory Alloys<sup>1</sup>**

5

**Transformation Properties**

	Transformation Temperature.....	-200 to 110°C
	Latent Heat Of Transformation.....	5.78 cal/g
10	Transformation Strain (for polycrystalline material)	
	for a single cycle .....	8% maximum
	for 10 <sup>2</sup> cycles .....	6%
	for 10 <sup>5</sup> cycles .....	4%
	Hysteresis* .....	30 to 50°C

15

**Physical Properties**

	Melting point .....	1300°C (2370°F)
	Density .....	6.45 g/cm <sup>3</sup> (0.0233 lb/in <sup>3</sup> )
	Thermal Conductivity	
20	austenite .....	0.18 W/cm · °C (10.4 BTU/ft · hr · °F)
	martensite .....	0.086 W/cm · °C (5.0 BTU/ft · °F)
	Coefficient of Thermal Expansion	
	austenite .....	11.9x10 <sup>-6</sup> /°C (6.11x10 <sup>-6</sup> /°F)
	martensite .....	6.6x10 <sup>-6</sup> /°C (3.67x10 <sup>-6</sup> /°F)
25	Specific Heat .....	0.20 cal/g · °C (0.20 BTU/lb · °F)
	Corrosion Performance** .....	excellent

**Electrical Properties**

	Resistivity (ρ)	
30	[resistance = ρ · length/cross-sectional area]	
	austenite .....	~100 μΩ · cm (~39.3 μΩ · in)
	martensite .....	~80 μΩ · cm (~31.5 μΩ · in)
	Magnetic Permeability .....	<1.002
	Magnetic Susceptibility .....	3.0x10 <sup>6</sup> emu/g

35

Table 2 (continued)

**Mechanical Properties**

	<b>Young's Modulus***</b>	
5	austenite .....	~83 GPa (~12x10 <sup>6</sup> psi)
	martensite .....	~28 to 41 GPa (~4x10 <sup>6</sup> to 6x10 <sup>6</sup> psi)
	<b>Yield Strength</b>	
	austenite .....	195 to 690 MPa (28 to 100 ksi)
	martensite .....	70 to 140 MPa (10 to 20 ksi)
10	<b>Ultimate Tensile Strength</b>	
	fully annealed .....	895 MPa (130 ksi)
	work hardened .....	1900 MPa (275 ksi)
	Poisson's Ratio .....	0.33
	<b>Elongation at Failure</b>	
15	fully annealed .....	25 to 50%
	work hardened .....	5 to 10%
	Hot Workability .....	quite good
	Cold Workability .....	difficult due to rapid work hardening
20	Machinability .....	difficult, abrasive techniques are
		preferred
* Values listed are for a full martensite to austenite transition. Hysteresis can be significantly reduced by partial transformation or ternary alloys.		
** Similar to 300 series stainless steel or titanium.		
25	***	Highly nonlinear with temperature.

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1 Design News, June 21, 1993 issue, p.77.

All the different specific formulations and metallic blends comprising nickel and titanium which yield a deformable, thermoelastic, shape-memory alloy composition are suitable for use when practicing the present methodology. All of these shape-memory alloys rely on a crystal phase change from a higher temperature Austenite form to a lower temperature Martensite form to accomplish the memory effect. The cubic Austenite phase behaves much like ordinary metals as it deforms. In contrast, the complex crystal Martensite form can be found by reversible movement of twin boundaries to change the average "tilt" or strain in each segment of the alloy. The overall strain can be eliminated by releasing the stress, by maintaining it if it is not thermally stable (the superelastic effect), or by healing the alloy to change it back to Austenite form (shape-memory effect).

The crystal transformation of shape-memory alloy compositions is, by definition, thermoelastic - i.e., it progresses in one direction on cooling below the transition temperature and in the other direction upon heating above the transition temperature. The amount of transformation change versus temperature, measured either as the percent of Martensite form or the strain in a constantly stressed element, is a function of and can be plotted against temperature (°C) directly; and the change from one phase (and identifiable shape) to another typically occurs in a narrow temperature range (often 5-10°C). Hysteresis takes place before the reverse transformation occurs.

The amount of strain accommodated due to the movement of twin boundaries, differs in each metallic alloy blending system. In the nickel-titanium system for example, up to 8% reversible tensile strain is available; however, to guarantee a long life use, the strain is often limited to 4-5%.

The stress-strain behavior of shape-memory alloy compositions is employed to help explain the shape-memory effect. For instance, Martensite is much easier to deform than Austenite. Therefore, one can deform the alloy while cold with much less force than when heated to change it back into Austenite form. As a result, the alloy converts thermal energy to mechanical work at high forces.

#### **Fixing the memory-shaped configuration in the metal alloy**

To prepare and fix the particular (or desired) shape to be "remembered" when the alloy undergoes a temperature phase transition, the alloy composition must be superheated initially to about 500°C (or roughly

930°F) for an hour while held in the fixed shape and position to be memorized. During the superheating process, the native alloy blend enters what is called the Austenite phase – a rigid lattice of nickel atoms surrounded by titanium alloys. Then, as the alloy metal cools below its transition  
5 temperature (which will vary with the percentage proportions of nickel and titanium), the alloy composition adopts the Martensite phase, in which the nickel and titanium atoms assume a very different arrangement – one that is very easy to bend and deform. Subsequently, when the deformed metallic alloy is reheated to the chosen transition temperature range between 25-35°  
10 C, thermal motion causes the atoms to snap back into the Austenite phase, thereby restoring the fixed memory-shaped configuration of the object [Invention & Technology, Fall 1993, pages 18-23].

For purposes of practicing the present in-vivo repair methodology, it is most desirable that the shape-memory alloy composition be prepared in a  
15 metallic blend and formulation such that the temperature transition phase occurs at a temperature less than about 35°C; but greater than about 25°C; and preferably be in the range from about 30-35°C. This preferred 30-35°C transition phase temperature range is dictated by the demands of the human body which maintains a normal temperature at about 37°C (98.6°F); and  
20 typically shows a normal temperature range and variance of one or two degrees Celsius above and/or below this normative temperature standard. It is for this reason that the broad temperature range be about 25-35°C and the preferred temperature transition occur in the range of 30-35°C; but that such transformation into the intended and fixed memory-shaped configuration  
25 occur at least by a temperature of 35°C to insure a safety margin of medical usefulness.

**The shaped configurations of the alloy cuff at temperatures less than 25-35°C and at temperatures greater than 25-35°C**

30 The shaped cuff configurations of the thermoelastic alloy composition at temperatures less than about 25-35°C (a temperature below its transition temperature at which the alloy exists in the Martensite phase) may take a broad variety of different lengths, diverse dimensions, and disparate overall configuration. Merely exemplifying the range and diversity of three-  
35 dimensional forms into which the thermoelastic alloy compositions can be shaped into a cuff or flange structure at temperatures below 25°C are those

illustrated by Figs. 23-26 respectively. For purposes of practicing the present invention, Figs. 23 and 24 are considered more preferred embodiments and constructions of the cuff-shaped alloy structures, while Figs. 25-26 respectively represent formats and fabrications of the deformed alloy compositions in less frequently utilized cuff-shaped configurations.

As illustrated and embodied by Figs. 23A and 23B, the deformable thermoelastic cuff 300 is a substantially cylindrical-shaped collar which is open at each of its ends 302, 304. The cuff 300 is hollow; is substantially round or oval (in cross-sectional view); and has a determinable first configuration and dimensions initially which are deformed at will into a second memory-shaped configuration when placed at a temperature greater than about 25-35°C.

It is most desirable that the thermoelastic material constituting the sidewall 306 of the cuff 300 be prepared and initially-shaped as a first-configuration along the axis AA' as shown within Fig. 23A; and that the thermoelastic material constituting the sidewall 306 be an open-weave pattern of a memory-shaped alloy rather than take form as a solid mass of thermoelastic alloyed material. For this reason, the sidewall 306 illustrated within Fig. 23A appears in the first configuration as an open meshwork of wires 308 which are intertwined to form a substantially hexagonal pattern. This open meshwork of wires 308 provides the desired resiliency, flexibility, and memory-shaped deformation capability (particularly along the axis AA') such that the upper portion of the sidewall 306 will become deformed and flaired outwardly on-demand to yield the memory-shaped second configuration constituting the flaired-lip deformity 310 shown by Fig. 23B.

It will be recognized and appreciated that the deformed cuff shown by Fig. 23B is merely the result of removing the cuff structure from a temperature less than 25-35°C and placing it into a temperature environment greater than about 35-35°C. Thus, solely as a consequence of the change in temperature, the uppermost portion 309 of the open meshwork of wires 308 above the axis AA' has become deformed such that the upper sidewall 309 adjacent to the open end 302 has expanded outwardly, flaired, and become bent into a curved lip configuration in the memory-shaped deformed state. Note that in Fig. 23B the open meshwork of wires constituting the lower portion 307 of the sidewall 306 at the other open end 304 remains relatively stable and substantially unaltered in its original shape and state; alternatively, however,

the lower sidewall portion 307 can be made to expand outwardly so that it will fit more tightly within the perforation in the vascular wall. The deformation thus is controlled and the forces preferably applied to the upper sidewall portion from the AA' axis to cause the outwardly extending, flaired lip result.

5 Moreover, the resulting flaired lip zone 310 retains structural strength and resiliency as an open meshwork of wires despite having been created by deformation. The ability of the cuff to be deformed in the manner illustrated by Figs. 23A and 23B respectively is a requisite and necessary attribute and characteristic of each embodiment and construction for the deformable  
10 thermoelastic cuff.

The construction and design for the thermoelastic cuff in the present invention is an example of the engineering principle that structural form follows intended function. As a requisite component part of the catheter apparatus and methodology for creating a bypass conduit in-vivo, the  
15 intended functions of the thermoelastic cuff are twofold in nature: (1) the temperature-deformable cuff is intended to engage and become joined to either a synthetic prosthesis or a previously excised vascular segment which will serve as the bypass graft in-vivo; and (2) the temperature-deformable cuff is intended to be positioned within the internal lumen of an unobstructed  
20 major blood vessel (such as the aorta) and become thermally deformed in-situ such that a portion of the cuff wall becomes positioned and secured to the internal lumen (the blood flow channel) of the unobstructed blood vessel permanently and in a fluid-tight manner. Thus, as illustrated by the embodiment of Figs. 23A and 23B, the uppermost region 309 of the alloy  
25 comprising the cuff 300 is deformed on-demand by warming to a temperature greater than 25-35°C; and deforms into a flaired outwardly bent form which is intended to be secured within the lumen of the unobstructed artery or vein. The undisturbed sidewall portion 307 of the cuff is retained in unaltered form for engagement and juncture to the conduit segment which will serve as the  
30 bypass graft.

Several attributes and characteristics are commonly to be shared among all embodiments and constructions of the thermally deformable memory-shaped cuff. These include the following:

(a) It is only required that the alloy material constituting the  
35 memory-shaped cuff be thermally deformable on-demand. For convenience and greater facility in achieving such temperature initiated deformity in the

- degree and at the time required, it is most desirable that the alloy composition forming the cuff be an open weave or meshwork rather than a solid alloy mass, which is considered to be more difficult to deform in a thermally-controlled manner. There is, however, no substantive restriction or limitation at any time or under any intended use circumstances which necessitates an avoidance of a solid mass of material, either as a single alloy sheet or as a laminated plank of alloy material. Accordingly, the choice of whether to use an open meshwork or a solid mass of thermoelastic alloy material is left solely to the discretion of the manufacturer and the surgeon.
- 10           (b)     The thermoelastic cuff need only be comprised of resilient, flexible, but deformable metallic alloy matter. A number of different alloys of various formulations may be usefully employed when making a deformable memory-shaped cuff suitable for use with the present invention. Among the desirable alloy formulations are those characterized by Table 2 above.
- 15           (c)     After the deformable cuff has been manufactured using resilient shape-memory alloy materials, the first configured cuff structure (prior to thermal deformation) may be covered to advantage with one or more biocompatible coatings. These biocompatible coatings are intended to water-tighten the article and to facilitate the sewing of the bypass conduit to the cuff
- 20           as well as to reduce the interactions of the immune system and tissue reaction with the bypass graft after it has been secured to the blood vessels in their appropriate locations in-vivo. Such biocompatible coatings are conventionally known; will reduce the severity and duration of immune or tissue reactions which frequently disrupt or interfere with bypass grafts; and
- 25           are considered desirable in a majority of use instances in order to minimize the body reaction to vascular bypass surgery. A representative listing of biocompatible coatings deemed suitable for use with the deformable thermoelastic cuff is provided by Table 3 below.

Table 3: Biocompatible Coatings

5	High temperature pyrogen-free carbon; Polytetrafluoroethylene (PTFE) and other polyhalogenated carbons; Fibronectin; Collagen; Hydroxyethyl methacrylates (HEMA); Serum albumins; and
10	Suprafilm (Genzyme Corp.)

(d) Although the embodiment of the memory-shaped cuff or collar prior to thermal deformation (exemplified by Fig. 23A) may appear as a geometrically regular and coherent structure, there is no requirement or demand that either the general structure or overall appearance of any configured cuff conform to these parameters. Accordingly, it will be recognized and understood that the deformable, shape-memory alloy cuff structure need not take form as a completely encircling band or collar of thermoelastic material. To the contrary, a U-shaped band or flange of alloy material where the sidewall does not overlap or join and where a gapped distance separates the arms of the band or flange is both permitted and envisioned. Moreover, although the cylindrical-shaped format of the cuff illustrated by Fig. 23 is highly desirable, there is no requirement that the diameter of the cuff prior to or after thermal deformation be constant or consistent over the entire axial length of the cuff. Thus, anisotropic cuff structures as well as isotropic constructions are intended and desirable. In this manner, the cuff in its initial state prior to thermal deformation may have a variable internal diameter over the axial length of the article in which one open end may be either greater or lesser in size than the other open end; and there may be multiple increases and decreases in diameter size successively over the entire axial length of the cuff itself. All of these variations in construction and structure are within the scope of the present invention.

To illustrate some of the modest variations and differences available and envisioned for a deformable thermoelastic cuff intended for use with the present invention, the alternative cuff embodiments illustrated by Figs. 24, 25 and 26 are provided. As shown within Figs. 24A and 24B, the first shaped configuration for the deformable cuff or collar 330 appears as a cylindrical-shaped article having two open ends 332, 334 and a rounded sidewall 336. The body of the sidewall 336 is an open meshwork of closed loops 338, each closed loop being joined at multiple points along its perimeter to at least one other closed loop – thereby forming an open grid meshwork. A notable feature of the cuff construction within Fig. 24A is the outer edges of the open ends 332, 334, each of which is formed by a closed loop which is more easily bent and thermally deformed than the closed-loop meshwork in the middle of the sidewall 336. In many instances, the availability of closed-loop edges 340, 342 provide an enormous benefit and advantage when thermal deformation of the cuff occurs in-situ within the internal lumen of an

unobstructed artery or vein. In addition, the cuff 330 of Fig. 24A has been memory-shaped to deform substantially at the midline along the axis BB' such that the upper most portion 339 of the cuff near the open end 332 and the edge 340 will deform and flair outwardly as a consequence of placing the cuff in a temperature environment greater than about 25-35°C.

The result of thermal deformation in-situ at a temperature greater than about 25-35°C is shown by Fig. 24B. The sidewall upper portion 339 has become deformed and bent from the open end 332 to about the midline axis BB'. However, the lower sidewall portion 337 has remained substantially unaltered overall its surface area from the midline axis BB' to the other open end 334. This memory-shaped second configuration illustrated by Fig. 24B is the thermally deformed structure suitable for attaching a bypass graft segment to the internal lumen of an artery or vein in-vivo.

A third embodiment of a thermally deformable cuff or flange is illustrated by Figs. 25A and B. As shown therein, the first configuration for the deformable cuff 360 illustrated by Fig. 25A and is formed primarily as a series of coiled wires 368 whose overlapping and intersecting junctures have been fused together to make a coiled unitary article. The deformable cuff 360 at temperatures less than about 25°C thus has two open ends 362, 364 and an open coiled sidewall 336 formed from the commonly fused coils of wire. The open lattice work of coiled wires 368 provides the flexible and resilient meshwork suitable for achieving the primary functions of the memory-shaped deformable cuff. The sidewall 366 also has been pre-stressed along the middle axis CC' such that the uppermost sidewall portion 369 will become bent and deformed outwardly when exposed to an environmental temperature greater than about 25-35°C.

The consequence of placing the coiled cuff 360 in an ambient temperature greater than about 25-35°C is shown by Fig. 25B. It will be appreciated that the second, memory-shaped configuration of Fig. 25B is intended to be an in-situ generated result, occurring typically within the internal lumen of an artery or vein in-vivo. Thus the flaired out uppersidewall portion 369 has become bent at nearly a 90 degree angle with respect to the lower sidewall portion 367; and the midline CC' will generally serve as the axis of thermal deformation and curvature for the coiled cuff 360.

Finally, a fourth alternative embodiment is provided by Figs. 26A and 26B in which a thermally deformable cuff or band 380 in the first configuration

is shown having two open ends 382 and 384. In this instance, however, the sidewall 386 of the cuff 380 is comprised of a solid sheet of material. Two other features are also included in this embodiment of the thermally deformable cuff due to its construction using a solid sheet of resilient material as the sidewall 386 for the cuff. The sidewall 386 has been preferably pre-scored to form cross-hatched squares over the axial length of the sidewall; and the pre-scored sidewall thus will deform far more easily and bend outwardly along the scored lines of demarcation as shown when the cuff is placed in an ambient temperature greater than 25-35°C. Similarly, the sidewall material has been pre-stressed along the midline axis DD' such that the upper most region 389 nearest the opening 382 will become bent far more easily and deform in a controlled fashion when and as required by the user.

The effect and consequences of disposing the cuff 380 in an ambient environment whose temperature is greater than about 25-35°C is shown by Fig. 26B. The uppermost sidewall portion 389 has thermally deformed into the memory-shaped second configuration; and become bent into a curved lip extending outwardly from the midline axis DD'. However, the lower sidewall portion 387 of the cuff 380 has remained substantially unchanged from its initial shape and size. The memory-shaped characteristics have thus generated an in-situ thermal deformation most suitable for the attachment of a bypass graft in-vivo.

## II. The Bypass Graft Material

Two major sources of conduits suitable for use as a bypass graft are presently known and available. These are: synthetic prosthetic channel sections and previously excised blood vessel segments.

The choice of graft conduit is crucial to the success of coronary artery bypass grafting surgery (CABG) because the patency of a coronary conduit is closely associated with an uneventful postoperative course and a better long-term patient survival. The standard vascular conduits used for CABG are excised blood vessel segments taken from the greater saphenous vein (GSA) or another leg or arm vein. An excellent substitute conduit for coronary bypass operations that can be available on demand is certainly the desire of every practicing cardiac surgeon. However, virtually every synthetic alternative to arterial conduits or autologous fresh saphenous vein conduits

has proved disappointing. Fortunately, patients with absolutely no autologous conduit are uncommon. Circumstances exist, however, that often necessitate the use of alternative synthetic conduits such as young hyperlipemic patients; as absent or unsuitable autologous internal mammary artery and greater saphenous vein as a result of previous myocardial revascularization, peripheral arterial reconstruction; and varicose vein ligation procedures. In the present era of increasing numbers of repeat coronary revascularizations, approximately 15% of patients requiring CABG are now in need of alternative synthetic conduits.

10

#### A. Synthetic Conduits

The desired characteristics of synthetic conduits used as bypass grafts are nonimmunogenicity, easy availability and storage, less risk of kinking (due to its stiffness), a less turbulent flow (due to uniform diameter), and an absence of branches.

The medical value of synthetic conduits as bypass grafts in-vivo has been substantially investigated. See for example: Foster et. al., Circulation 79 (Sup 1): 134-139 (1989); and Canver, C.C., Chest 108: 1150-1155 (1995); and the other references cited below. A summary review of the recent reports evaluating these conduits thus is in order.

Historically, Sauvage and associates in 1976 [J. Thorac. Cardiovasc. Surg. 72: 418-421 (1976)] described the placement of a 4.0-cm long, 3.5-mm diameter knitted Dacron filamentous vascular prosthesis as an interposition graft between the aorta and right coronary artery during repair of a vascular aneurysm of the ascending aorta in an adult. The graft was demonstrated to be patent by angiography 16 months after operation. A literature search at the time found only two other prior reports of successful aortocoronary grafting with synthetic conduits, both involving children with congenital coronary defects. Two factors present in all three cases that were suggested as promoting long-term patency were that only short segments of prosthetic graft were placed, and that they were implanted as interposition grafts from the end of the coronary artery to the aorta.

The initial results of CABG with expanded polytetrafluoroethylene (PTFE) (Gore-Tex. W.L. Gore and Associates, Elkton, Maryland) grafts were encouraging; however, this impression was based on single-case reports or

35

series with small numbers of patients. Molins and co-authors in 1978 [J. Thorac. Cardiovasc. Surg. 75: 769-771 (1978)] presented a patient in whom they had constructed a bypass to the distal right coronary artery with a 4.0 mm diameter PTFE graft, found patent on catheterization 3 months after surgery. Also, Yokoyama and associates in 1978 [J. Thorac. Cardiovasc. Surg. 76: 552-555 (1978)] described five aortocoronary bypass patients in whom 3.0-5.0-mm PTFE grafts had been used. Four of five of these grafts were open on restudy 3-6 months postoperatively. Subsequently, Islam and colleagues in 1981 [Ann. Thorac. Surg. 31: 569-573 (1981)] reported that a 6-mm diameter PTFE graft used for aorta-to-right coronary artery bypass remained widely patent on repeat angiography 18 months after surgery.

An indication of the early and midterm results of CABG with PTFE grafts was provided in the 1981 report of Sapsford and associates [J. Thorac. Cardiovasc. Surg. 81: 860-864 (1981)]. Twenty-seven coronary bypasses were constructed in 16 patients with 4.0-mm PTFE grafts. Eleven patients were restudied at 3 months after surgery, and a 61% (11 of 18) graft patency rate was found, in six patients who had repeat angiography 12-29 months after CABG, six of nine PTFE grafts were open. Then, Murta and co-authors in 1985 [Ann. Thorac. Surg. 39: 86-87 (1985)] detailed a single case experience where two 4.0-mm diameter PTFE aortocoronary grafts remained present 53 months postoperatively. More recently, Chard and associates reported in 1987 [J. Thorac. Cardiovasc. Surg. 94: 132-134 (1987)] long-term patency results with PTFE aortocoronary grafts. Using both one-to-side and multiple, sequential, side-to-side anastomoses, they constructed a total of 28 distal coronary grafts in eight patients. Patency rates on repeat angiography were 64% (18 of 28) at 1 year, 32% (9 of 28) at 2 years, 21% (6 of 28) at 3 years, and 14% (4 of 28) at 45 months.

The choices of materials recognized as being suitable for the making of a biocompatible synthetic conduit are quite limited. These are provided by Table 4 below.

#### B. The Excised Blood Vessel Segment

A variety of blood vessel segments excised from the vascular system in-vivo are suitable for use as bypass graft conduits. A representative, but incomplete, listing is provided by Table 5 below.

Table 4: Synthetic Conduit Materials

Synthetic Substances

- 5      Dacron (knitted or woven) polymer;  
Polytetrafluoroethylene or "PTFE" (knitted or woven);  
Impra;  
Teflon polymer; and  
Kevlar polymer.

Table 5: Vascular Conduits For Bypass Grafting

Venous Conduits

- (a). Autologous vein conduits.
- 5                    Greater saphenous vein segments;  
                     Lesser saphenous vein segments;  
                     Upper extremity (cephalic and basilic) vein segments.
- (b). Nonautologous vein conduits.
- 10                   Umbilical vein segments;  
                     Greater saphenous vein homografts.

Arterial Conduits

- (a). Autologous arterial conduits.
- 15                   Internal mammary artery segments;  
                     Right gastroepiploic artery segments;  
                     Inferior epigastric artery segments;  
                     Radial artery segments;  
                     Splenic artery segments;  
                     Gastroduodenal artery segments;
- 20                   Left gastric artery segments;  
                     Intercostal artery segments.
- (b). Nonautologous arterial conduits.
- Bovine internal thoracic artery segments.

The preferred sources of blood vessels suitable for use as a vascular bypass graft are the saphenous veins. These veins constitute the superficial veins of the lower extremities and comprise both the greater (or long) saphenous and the lesser (or short) saphenous veins. Anatomically, the long saphenous vein begins on the medial side of the foot and ends in the femoral vein below the inguinal ligaments; and the short saphenous vein begins behind the lateral malleolus and runs up the back of the leg to end in the popliteal vein. However, if the saphenous veins of the particular patient are unsuitable or unavailable for any reason, either the cephalic or the basilic veins are very acceptable substitutes for use as a vascular bypass conduit. However, if these leg or arm veins are not available, synthetic or other biologic materials may also be used as substitutes.

The medical procedure to isolate and excise the saphenous vein of choice is conventionally known and considered a routine surgical technique. The saphenous vein is harvested under general anesthesia. An incision is first made in the medial malleolus, where the saphenous vein is often dilated. The saphenous vein is identified and then dissected with a single incision made along its course with scissors. Branches are doubly clamped with hemostatic clips and divided. The saphenous vein is then freed up and removed from the leg. The leg wound is closed with subcutaneous sutures and Steristrip adhesive over the incision. The vascular segment is prepared on a separate sterile table with adequate light and loupes, and branches are selectively ligated with 4-0 silk. An oval-tip needle on a syringe is inserted into the graft to gently dilate it by administering a balanced electrolyte solution (pH 7.4, chilled to 7° to 10° C) and 10,000 units/liter of heparin. A valvulotome is inserted into the vein graft segment and the valves clipped with a 3-mm right-angle stainless steel instrument with a highly polished ball tip on the right angle. The knife edge is protected and sharply splits the cusp, causing valvular incompetence. Measurements for the approximate lengths of the grafts may be made with umbilical tapes, and the appropriate lengths may be chosen before it is sewn to the cuff and coronary arteries.

### III. The Introducer System

The introducer system comprises the catheter apparatus including the thermoelastic deformable cuff and a bypass conduit in combination; and it is this introducer system which is utilized by the surgeon to perform the

requisite acts and manipulations by which the bypass conduit is delivered to and becomes secured within the lumen of the unobstructed major blood vessel (and subsequently anastomosed to the obstructed blood vessel at a site distal to the obstruction). For descriptive purposes and for increased clarity of comprehension, this description will intentionally limit itself to the use of the variable-sized obturator illustrated by Figs. 9 and 10 respectively; to the thermally deformable cuff structure illustrated previously by Figs. 23A and 23B respectively; and to the use of a previously excised vascular segment taken from the long or short saphenous vein in the same patient.

10 The introducer system represents and provides for the intentional placement and carriage of the bypass conduit on the obturator, the engagement and juncture of the deformable cuff to one end of the bypass conduit prior to grafting in-vivo; and the proper orientation of the then engaged cuff/bypass conduit together on the obturator with respect to its relationship to the puncturing headpiece.

15 The preferred introducer system begins with the proper placement of a previously excised vascular segment (desirably taken from the saphenous vein) upon the obturator. This initial manipulation is illustrated by Fig. 27 in which a previously excised vascular segment 400 having two open ends 404 and 406 is placed upon the elongated shaft 134 adjacent to but preferably not in direct contact with the base plate 126 of the puncturing headpiece 122 of the obturator (previously shown by Figs. 9 and 10 respectively). As shown by Fig 27, it is intended and preferred that the elongated shaft 134 be inserted at the proximal end 138 into the internal lumen 402 of the excised vascular segment 400 by the surgeon; and that the body of the vascular segment 400 (comprising the portions 410 and 412) then be conveyed over the axial length of the elongated shaft 134 until the open end 404 and vascular portion 410 are at a chosen position, typically 1-2 centimeters from the distal end adjacent to the puncturing headpiece 122. In this manner, the weight and body of the excised vascular segment 400 is carried on the elongated shaft 134; and it is desirable that the diameter of the elongated shaft 134 be smaller than the overall diameter of the internal lumen 402 for the vascular segment 400. As a consequence of this placement, the excised vascular segment is adequately supported, carried, and transported by the elongated shaft during the entirety of the manipulations prior to entry into the body of the living patient as well as subsequent to the in-vivo perforation of the

unobstructed major artery or vein. The manipulation illustrated by Fig. 27 is expected to be performed by the surgeon immediately after excising the vascular segment from the patient but prior to beginning the bypass graft surgery itself.

- 5       After the excised vascular segment 400 has been properly positioned on the elongated shaft 134 of the obturator 120, the deformable cuff 300 (illustrated by Fig. 23 and described in detail previously herein) is desirably passed over the puncturing headpiece 122 and over the open end 404 to cover the small portion 410 of the exterior surface over of the excised
- 10       vascular segment 400. This is illustrated by Fig. 28. It is desirable (but not absolutely necessary) that a gap distance "g" (about 1-2 centimeters) separating the open end 404 from the puncturing headpiece 122 be maintained during the placement of the deformable cuff — as this will allow for easier positioning of the thermally deformable cuff in a pre-chosen alignment
- 15       and posture and in a more controlled manner of deformation on-demand.

- When the deformable cuff has been positioned over the vascular segment to the satisfaction of the surgeon, the lower sidewall portion 307 of the cuff covering the exterior surface 410 nearest the open end 404 of the excised vascular segment 400 must be physically engaged and become
- 20       joined to the vascular segment in a reliable and safe manner. This is also illustrated by Fig. 28. One preferred manner of engagement and juncture is for the surgeon to suture the open meshwork sidewall 306 of the cuff 300 directly to the portion 410 of the excised segment 400. This suturing is easily performed by the surgeon prior to beginning the grafting surgery and each of
- 25       the sutures 420 will serve as the physical means for engaging and permanently joining a portion of the open meshwork of wires in the sidewall of the cuff to the excised vascular segment itself. The type of sutures 420, their placement, their number, and the linkage to the vascular wall of the excised segment are left to the personal discretion and choice of the surgeon.

- 30       Other means for permanent engagement and juncture of the thermally deformable cuff to the vascular wall of the excised segment also are commonly available. These include surgical staples; biocompatible adhesives; encircling ligatures; and a wide range of surgical fasteners and closures. Any and all of these alternatives may be employed alone or in
- 35       combination to achieve a reliable engagement and juncture.

One optional variation of the introducer system provides that the open meshwork sidewall 306 of the cuff 300 can be covered with synthetic materials to facilitate the suturing, stapling or other means for attaching the prosthetic channel section or vascular segment to the cuff. These  
5 biocompatible synthetic materials can be applied in one or more layers or coatings to the cuff; and serve as an overlay for a portion or the entirety of the cuff sidewall.

In addition, another optional variation of the introducer system allows the sidewall of the cuff to be positioned within the lumen of the prosthetic  
10 channel section or excised vascular segment. In these instances, the meshwork sidewall of the cuff is incorporated within the interior of the prosthetic conduit or vascular bypass segment in order to eliminate the need for direct sewing of the bypass conduit to the cuff. This variant thus offers a simplified procedure for locking the cuff to the bypass conduit in a permanent  
15 fashion.

After the deformable cuff 300 has been engaged and joined to one end of the excised vascular segment 400 then carried upon the elongated shaft 134 of the obturator, the size of the puncturing headpiece 122 should be adjusted in shape and girth such that the diameter of the base plate 126 of  
20 the puncturing headpiece 122 preferably is equal to or slightly greater than the diameter of the open cuff end 302. This manipulation is also illustrated by Fig. 28 where the size of the base plate 126 is coextensive in diameter with the diameter of the open end 302 of the deformable cuff. In this preferred manner, the entirety of the puncturing headpiece 122 serves as a front  
25 section or first stage for the introducer system as a whole.

The complete introducer system is illustrated by Fig. 29 in which the fully prepared obturator carrying the previously excised vascular segment to be used as a bypass conduit and the thermally deformable cuff have been positioned in advance; and the prepared obturator has been placed within the  
30 internal lumen of a catheter. As seen therein, the catheter appears in an exposed, cross-sectional view and shows the hollow tube 2 of fixed axial length having a discrete proximal end (not shown), a discrete distal end 10 and an internal lumen 14 of pre-determined diameter sufficient to house the entirety of the prepared obturator (illustrated by Fig. 28). The distal end tip  
35 10 of the catheter is adapted for direct delivery of the catheter in-vivo to a chosen site where an unobstructed artery or vein is in anatomic proximity to

an obstruction lying within another blood vessel; and the prepared obturator of Fig. 28 (comprising the previously excised blood vessel segment and the deformable cuff) lies within the internal lumen 14 of the catheter. The introducer system shown by Fig. 29 is complete; and the surgeon may now  
5 begin the first steps for surgically delivering the introducer system into the thoracic cavity or other appropriate body region in order to create the bypass graft.

10 Maintaining the ambient temperature of the internal lumen of the catheter at less than about 25-35°C

The preferred means for cooling and maintaining the temperature of the internal lumen in a guiding catheter comprising the introducer system at less than about 25-35°C during the creation of a bypass graft in-vivo is via the use of cold physiological-strength (0.85-0.9%) saline. Typically, a sterile  
15 saline pack is refrigerated in advance of the repair surgery and cooled to a temperature between 40-50°F (5-10°C). The cooled saline is then infused by the surgeon into the internal lumen of the catheter in order to cool the thermally deformable cuff both initially and periodically during the surgery. The sterile saline is compatible with the living tissue of the patient; and  
20 multiple applications of saline can be introduced into the internal lumen volume of the catheter as often as deemed necessary without meaningful risk to either the introducer system or the patient.

As an alternative to the use of saline infusion, any other suitable means for cooling (such as gaseous carbon dioxide) may also be employed  
25 as a less preferred practice for maintaining the environmental temperature of the internal lumen volume of a catheter at less than about 25-35°C. Such alternative procedures, however, are often less desirable due to the effects of potential direct contact and possible biological reaction when intentionally or inadvertently released into the bloodstream or other highly vulnerable organs  
30 and tissues of the body. Nevertheless, the use of alternative means to reduce the environmental temperature of the internal lumen volume of a catheter to less than about 25-35°C can be safely and properly performed in many different medical circumstances using the present invention.

#### **IV. The Routing And Surgical Introduction Of The Controlling Catheter Into The Body Of The Living Human**

Catheterization involves a great deal of technical skill, some instrumentation and mature judgment in order to choose among the  
5 appropriate procedures and the various techniques which are now conventionally known and available for use. Clearly, because the present technique constitutes catheter intervention in critically ill patients, the physician or surgeon must be very familiar with the available anatomical  
10 alternatives in order to select the best routing for introducing the catheter, the best technique in order to access the thoracic cavity of the body where the obstructed artery and aorta exist, and to carefully select the timing and other operative conditions in order to achieve best results.

In general, catheterization can be performed using any duct, tube, channel, or passageway occurring naturally or surgically created for the  
15 specific purpose. Thus, among the naturally occurring passageways in the body are the anus; the alimentary canal; the mouth, ear, nose, or throat; a bronchus of the lung; the urethra; the vaginal canal and/or cervix; and any blood vessel of sufficient size of the central circulation in the body. Any of these routings are envisioned and expected to be used when and if  
20 appropriate. However, clearly a commonly used and the critical route of access is the introduction of catheters into the thoracic cavity and the arterial blood circulation adjacent to the heart.

For this reason, it is useful to briefly summarize the technique currently in use for introduction of catheters into the central blood circulation as an  
25 illustrative example of preferred catheterization techniques. There are two general methods currently in use. These are: (a) percutaneous introduction using needles and guidewires; and (b) direct introduction after surgical isolation of the blood vessel of choice. While either general method may be utilized at any site of the general circulation, practical and anatomical  
30 considerations will generally dictate which approach is most appropriate under the individual circumstances.

##### **The modified Seldinger Technique:**

The percutaneous introduction of a catheter is illustrated by the  
35 modified Seldinger technique which is shown by Figs. 30A-30F respectively. Fig. 30A shows a blood vessel being punctured with a small gauge needle.

Once vigorous blood return occurs, a flexible guidewire is placed into the blood vessel via the needle as shown by Fig. 30B. The needle is then removed from the blood vessel, the guidewire is left in place, and the hole in the skin around the guidewire is enlarged with a scalpel as shown by Fig.

5 30C. Subsequently, a sheath and a dilator is placed over the guidewire as shown by Fig. 30D. Thereafter, the sheath and dilator is advanced over the guidewire and directly into the blood vessel as shown by Fig. 30E. Finally, the dilator and guidewire is removed while the sheath remains in the blood vessel as illustrated by Fig. 30F. The catheter is then inserted through the  
10 sheath and fed through to reach the desired location.

The other general method for the introduction of catheters into the blood circulation is a direct surgical cutdown. Cutdown procedure is often a complex invasive surgery and is used only no direct access is generally available. A far more complete and fully descriptive review of both these  
15 general catheterization techniques is provided by the texts of: Diagnostic And Therapeutic Cardiac Catheterization, second edition, 1994, Chapter 8, pages 90-110 and the references cited therein.

Accordingly, for purposes of practicing the present methodology, any and all conventionally known general catheterization procedures and  
20 techniques which are conventionally known and in accordance with good medical practice are explicitly intended to be utilized as necessary in their original format or in a modified form. All of these general catheterization routing and use techniques are thus envisioned and are deemed to be within the scope of the present invention.

25

General rules for choosing an appropriate site of body entry:

An axiomatic or general set of rules by which a surgeon or radiologist can chose a proper or appropriate site of entry for introducing the guiding catheter into the body of a patient for purposes of creating a vascular bypass  
30 in-vivo is as follows: (a) always pick the shortest and straightest pathway possible or available; (b) identify the chosen entry site on an existing and accessible unobstructed artery or vein, the larger the diameter of the unobstructed artery or vein the better; and (c) identify the location and orientation of the obstruction in the obstructed artery or vein and chose an  
35 entry site distal to the obstruction.

A favored approach to introducing the guiding catheter into the thoracic aorta:

Using the ascending aorta approach as a representative illustration and example:

- (1) Under general anesthesia, the chest of the patient is prepared and draped in a sterile fashion.
- (2) A three-inch incision is made to the left or right of the breast bone through which the surgeon operates.
- (3) Three additional one-inch incisions then are made to insert a video camera, knife, surgical stapler, and other instruments.
- (4) The ribs are separated, the thoracic cavity is entered, and the ascending thoracic aorta is exposed.
- (5) The introducer system is then positioned at the chosen site on the ascending thoracic aorta.

**V. The In-Vivo Placement Of The Vascular Bypass Graft Into The Lumen Of The Unobstructed Major Blood Vessel**

The method of the present invention utilizes the introducer system via the catheterization technique to create a bypass graft conduit between a major unobstructed blood vessel such as the aorta and an obstructed blood vessel in-vivo using a previously excised vascular segment as a conduit. This procedure is illustrated by Figs. 31-39 collectively. It will be recognized and appreciated, however, that while Figs. 31-39 exemplify and illustrate the manipulations of the surgeon and the events in sequence leading to the creation of a vascular bypass, this description and the figures themselves present a greatly simplified presentation and explanation of the medical procedure, the technical skills required, and the safety measures taken for the patient's benefit medically. The use of synthetic conduits and fixed-size obturators, although not described, is also within the scope of the present methodology.

After the introducer system catheter has been routed and surgically delivered into the body of the living human in the manner described previously herein, the first stage for the process is reached as shown by Fig. 31. The illustration of Fig. 31 (as well as Figs. 32-40 respectively) are shown as partially exposed views in order to show more easily the detailed placement and orientation of the introducer system comprising the prepared

obturator carrying the thermally deformable cuff and previously excised vascular segment in combination.

As seen within Fig. 31, a major artery such as the aorta 500 is shown in partial cross-sectional exposed view to reveal the thickness of the arterial wall 502 and the internal lumen 504. The catheter and the prepared obturator comprising the introducer system are as described in detail previously herein and illustrated by Fig. 29. It will be noted that the puncturing headpiece 122 of the obturator 120 is positioned within the lumen of the catheter such that the perforating end tip 130 is in direct contact with the arterial wall 502 at the chosen anatomic site. The puncturing headpiece 122 is of sufficient size such that the entirety of the thermally deformable cuff 300 and the joined vascular segment 400 lie directly behind and are in axial alignment with the puncturing headpiece 122 and the elongated shaft 134. When positioned as shown by Fig. 31, the prepared obturator has been cooled to a temperature less than about 25°C (using cold saline or gaseous carbon dioxide), and is properly placed for piercing and penetrating the arterial wall on-demand.

When the surgeon extends the prepared obturator within the cooled and temperature controlled internal lumen of the catheter, the result is illustrated by Fig. 32. As seen therein, the perforating end tip 130 has punctured and pierced through the arterial wall 502; and been advanced into the arterial lumen 504. The initial pierced hole in the arterial wall 502 made by the perforating end tip 130 is widened into a passageway as a consequence of the entire puncturing headpiece 122 following the entry path created by the perforating end tip. As the puncturing headpiece 122 penetrates through the arterial wall 502, the size of the puncture in the arterial wall becomes widened and enlarged to conform to and accommodate the configuration and the girth of the puncturing headpiece in its entirety. The configuration and overall size of the puncturing headpiece 122 thus serves as the means for enlarging the initial puncture made by the perforating end tip 130 such that the entire girth and overall diameter of the obturator (complete with thermally deformable cuff and excised blood vessel segment in combination) can subsequently pass through the enlarged hole in the arterial wall.

As the prepared obturator is extended further across the thickness of the arterial wall 502 through the enlarged passage, the penetrating

headpiece 122 is desirably extended farther into the arterial lumen 504 until at least the upper sidewall portion 309 of the thermally deformable cuff 300 also has been advanced far enough to lie within the internal lumen of the blood vessel. This sequence of events and result is illustrated by Fig. 33.

5 Then the surgeon slowly and carefully withdraws the catheter 2 from the passageway in the arterial wall 502 while maintaining the components of the prepared obturator in a stationary position. Consequently, the upper sidewall portion 309 of the cuff 300 is slowly released into the arterial lumen 504 from the internal lumen 14 of the receding catheter 2 and the  
10 thermoelastic alloy comprising the cuff 300 begins to deform in-situ into the second memory-shaped configuration. This manipulation and result is illustrated by Fig. 34.

As seen therein, the surgeon has activated the means for contracting the girth of the puncturing headpiece; and partially withdrawn the catheter  
15 such that the uppermost part of the cuff has been released into the warm temperature environment of the arterial lumen in-vivo. Thus Fig. 34 shows the beginning of thermal deformation for the cuff in-situ within the arterial lumen.

Fig. 34 also shows that the puncturing headpiece 122 has been  
20 reduced in overall size and shows a diminished diameter or girth in comparison to its initial size as shown previously via Figs. 30-33 respectively. The reduced overall size and altered configuration of the puncturing headpiece 122 lying disposed within the arterial lumen in-vivo is a preferred manipulation of the methodology provided by the use of variable-size  
25 obturators.

Alternatively, the puncturing headpiece 122 may be fixed in both size and shape; and the thermally deforming sidewall of the cuff 300 will be made to expand outwardly along its length in order to allow the fixed-size  
puncturing headpiece to pass through the outwardly expanded cuff diameter.  
30 Also, the outward expansion by the deformed cuff can improve and enhance watertightness between the cuff 300 and the arterial wall 502.

After the puncturing headpiece has been desirably reduced in overall size and has a diminished girth, the overall diameter of the contracted  
puncturing headpiece 122 is smaller in overall size than the diameter of the  
35 thermally deformable cuff disposed directly behind the headpiece. Due to the reduced size of the puncturing headpiece 122, the thermally deforming cuff

and engaged vascular segment carried upon the elongated shaft 134 of the obturator may then be controllably and completely released by withdrawing the distal end 10 of the catheter from the warm temperature environment of the arterial lumen 504. This manipulation and result is illustrated in Figs. 34 and 35.

It is important to recognize and note that a meaningful portion of the upper sidewall of the thermoelastic cuff 300 has been released out of the catheter lumen into the arterial lumen 504 as illustrated by Fig. 35. Concomitant with the controlled release of the thermoelastic cuff 300 into the arterial lumen 504, two consequential events also occur: (a) the engaged and joined vascular segment 400 is concurrently placed and fitted into the enlarged puncture or hole in the arterial wall 502 at the chosen site; and (b) the upper sidewall portion 309 of the cuff, as it is freed from the confinement of the internal lumen of the catheter and placed in a warm temperature environment above 35°C, begins to deform thermally into the memory-shaped second configuration.

The degree of extension and rate at which the engaged cuff and the vascular segment is controllably released from the catheter lumen lies at the discretion of the surgeon performing this methodology. If the surgeon so chooses, the deformable cuff and the excised vascular segment may be extended through the thickness of the arterial wall but not far or completely into the arterial lumen itself. In the alternative, the surgeon may choose to advance the engaged cuff and vascular segment extensively or completely and thus position the upper sidewall portion of the cuff as far as possible within the internal lumen of the artery itself. The degree of entry as well as the rate of release of the deformable cuff and the engaged vascular segment into the warm temperature environment above 35°C of the arterial lumen thus is the choice and judgment of the surgeon at all times.

After the thermoelastic cuff 300 and the engaged vascular segment 400 have been advanced such that each has penetrated the arterial wall 502 and at least a portion of the upper sidewall 309 of the deformable cuff 300 has been released into the arterial lumen, to the surgeon's personal discretion and accommodation, the uppermost region 309 of the deformable cuff 300 will thermally deform in-situ into the memory-shaped second configuration -- as shown by Fig. 36. The warm temperature environment above 35°C of the arterial lumen has caused the upper sidewall 309 of the

cuff to deform in-situ; to become bent outwardly; and to become flaired and flattened out within the internal lumen 504 of the artery 500. Then, as the memory-shaped second configuration for the cuff appears in an ever greater degree, the sidewall 309 of the cuff 300 will become more flattened; will come  
5 to lie substantially against the interior surface of the arterial wall 502; and will become secured to the arterial wall in a permanent manner. This consequence and result is also illustrated by Fig. 36.

The controlled thermal deformation and flairing of the uppermost sidewall 309 of the cuff 300 occurs in-situ within the warm, blood flow channel  
10 of the artery and the act of controlled deformation is performed without substantially diminishing the rate of blood through the lumen of the artery or causing the heart of the patient to stop at any time. The intentional and controlled thermal deformation of the cuff along its upper sidewall as it lies  
15 disposed within the arterial lumen causes a permanent flairing of the open meshwork of wires forming the sidewall. The deformed sidewall is bent, maneuvered, and flaired in-situ solely by the warming of the memory-shaped alloy comprising the cuff to a temperature above 35°C. No tool, article, or mechanical device is needed or utilized in order to cause a controlled deformation of the cuff while disposed within the blood channel of the artery  
20 in-vivo.

After the cuff has been thermally deformed within the arterial lumen 504 and become secured to the interior surface of the arterial wall 502 to the personal satisfaction of the surgeon, the puncturing headpiece 122 and the obturator as a whole can be removed. The surgeon is confident that the  
25 overall diameter of the contracted puncturing headpiece is smaller than the diameter of both the cuff and the engaged vascular segment; and therefore, the puncturing headpiece will then be able to enter and pass completely through the fully deformed cuff and the internal lumen of the engaged vascular segment in-situ without meaningfully injuring or altering the internal  
30 surface of the blood flow channel itself.

The act of removing the obturator is quickly accomplished by the skilled surgeon; and the act of removal serves to isolate the now fully deformed sidewall 309 of the cuff 300 secured to the interior surface of the arterial wall 502. The deformed cuff 300 and the engaged vascular segment  
35 400 remain permanently secured and attached to the blood flow channel of the major artery in a manner which permits arterial blood to enter through the

deformed cuff into the internal lumen of the vascular segment without meaningful major alteration of the primary artery and without major destruction of vascular tissues at the site of graft bypass juncture. To ensure that the placement of the deformed cuff and engaged vascular segment is

5 fluid-tight, the surgeon then preferably applies a biocompatible adhesive 530 to the exterior surface of the arterial wall 502 at the puncture site. The biocompatible adhesive 530 is desirably spread over the sidewall 306 of the cuff 300 at the exterior surface of the arterial puncture site. This act and result is shown by Fig. 37. The applied biocompatible adhesive dries quickly;

10 forms a permanent and fluid-tight seal at the puncture site; and will not degrade or cause irritation to either the artery wall or the grafted vascular segment now to be used as a bypass conduit. Note also that the catheter has desirably also been removed prior to the placement of the biocompatible adhesive at the puncture site on the arterial wall. This catheter removal step

15 is preferred in order to have better access to the thermally deformed cuff at the point of juncture.

A number of different biocompatible adhesives may be employed to seal permanently the puncture site in the manner shown by Fig. 37. A representative but non-exhaustive listing of such biocompatible adhesives is

20 provided by Table 6 below.

Table 6: Biocompatible Adhesives

Adhesives Materials

5	Fibrin glue; Histacryl (butyl-2-cyanoacrylate) tissue adhesive; Cyanoacrylates; Liquid silicones; Epoxy resins; and
10	Polyurethane adhesives.

The overall result of this procedure is illustrated by Fig. 37 in which the uppermost region 309 of the cuff sidewall has been thermally deformed in-situ and become flaired outwardly into the internal lumen 504 of the artery 500. The open meshwork of wires 308 has aided and assisted the ease and speed by which the deformed sidewall 309 has been bent, become extended into the internal arterial lumen, and become secured in-situ to the interior surface of the arterial wall 502. Also, the placement of the biocompatible adhesive 530 at the puncture and graft juncture site places the bypass conduit in a fluid-tight setting permanently such that the engaged vascular segment 400 is attached to and is in blood flow communication with the arterial blood in an unobstructed manner. The placement and securing of the vascular bypass conduit to the major unobstructed artery is thus complete in all respects.

The other end of the excised vascular segment 400 typically is then conventionally attached to the obstructed blood vessel at a chosen site distal to the obstruction itself as illustrated by Fig. 39. The manner of joining the second open end of the grafted vascular segment to the obstructed artery or vein may be achieved conventionally by anastomosis; with or without sutures; and with or without use of tissue adhesives by the surgeon. It will be noted and appreciated also, that the surgeon, at his option, may in fact intentionally create an aperture in the wall of the grafted vascular segment 400; introduce the obturator 120 into the internal lumen of the vascular segment; place a second deformable cuff 300 in proper position; and then engage the cuff to the second open end of the vascular segment in the manner described previously. If the surgeon so chooses, therefore, the entirety of the introducer system and the catheterization methodology may be repeated for use at the chosen site on the obstructed blood vessel. Nevertheless, it is generally expected that in most instances, the surgeon will prefer to perform conventional anastomosis as the means for joining the other open end of the blood vessel segment to the obstructed artery or vein. This is illustrated by Fig. 39.

The entire catheterization methodology for creating a vascular bypass graft or shunt has been shown and described in detail via Figs. 32-39 inclusive. Each essential manipulation or required act has been illustrated in detail and described in depth. Nevertheless, to assure a complete and comprehensive presentation of the methodology as a whole, a summary

recitation of the preferred surgical procedures using the catheter apparatus, the introducer system, and the methodology is provided hereinafter.

**VI. SUMMARY OF THE PREFERRED SURGICAL PROCEDURES USING  
THE CATHETER APPARATUS AND METHOD.**

The catheter apparatus and methodology comprising the present invention provides an approach designed to allow surgeons do multiple bypass using vein bypass grafts in a minimally invasive way. This procedure allows a simpler way to place the vein grafts proximally to the aorta and distally to the coronary artery without using a heart-lung machine and without need for stopping the heart. Small incisions are first made between the ribs; a video camera and instruments with long handles are inserted; and, under the direct visualization, the aorta is punctured to create a proximal graft to anastomosis (aortotomy) using a specially prepared catheter introducer system which internally carries a deformable cuff and a previously excised vascular segment.

The thermally deformable cuff is made of nickel-titanium alloy wire mesh; and is preferably coated with prosthetic material such as PTFE. The cuff will become anchored by thermal deformation at a temperature above about 35°C inside the aortic wall and be secured and blood-leak-proven outside the aortic wall by subsequently applying a tissue adhesive. This thermally deformed cuff will provide a secure sutureless aortic anastomosis for the bypass vein graft. The proximal part of the vein graft is preferably sewn to the cuff. The bypass graft is then distally anastomosed to the coronary artery, which can be done either by the conventional way with sutures or by applying tissue adhesive between the adjacent outer walls of the bypassable coronary artery and the bypass vein graft without sutures.

This unique procedure simplifies the complexity of the conventional coronary artery bypass surgery and makes the surgery less invasive. Moreover, this technique provides a critical advantage over the conventional bypass surgery (using excised vein grafts), or the thoracoscopic minimally invasive surgery (using an internal mammary vein graft). Also, it will shorten the operation time and make the coronary bypass surgery safer and more cost-effective.

**Thoracotomy and Aortocoronary Bypass:**

After cutting through the muscle and other tissue of the anterior chest, the surgeon separates a rib from the breast bone and cuts a piece of the cartilage at the detached end to provide working space for the aortotomy and placement of the proximal graft anastomosis.

The bypassing of the vascular blockage increases blood flow to the heart. The optimal environment for the vascular anastomosis is a motionless, dry field. In conventional coronary bypass surgery, this environment can be obtained by total cardiopulmonary bypass and cardioplegia techniques to arrest the heart. However, in minimally invasive coronary bypass surgery, it is performed without cardiopulmonary bypass and without stopping the heart. Instead, the heart beat is slowed down with cardiac medications such as calcium channel blockers and beta-blockers, and with hypothermia.

**Creation of the proximal anastomosis**

The ascending aorta is first palpated before creation of the aortotomy to determine the proper location of the aorta for aortotomy and delivery of the introducer system. The ascending aorta is preoperatively evaluated by means of CT scan or MRI to exclude the patient with severe atherosclerosis of the aorta, which may interfere with creation of the aortotomy and increase possible associated complications such as dissection and embolization of the plaques. When the ascending aorta is shown to be moderately thick by CT or MRI, the deformable cuff is larger (7 to 8 mm outer diameter) than usual (5 to 6 mm outer diameter) and may be placed in the aorta to prevent narrowing at the proximal anastomosis.

This technique involves safe and simple placement of the proximal anastomosis of the vein graft without clamping of the aorta and without using heart-lung machine. The proximal part of the ascending thoracic aorta is first exposed and punctured with an obturator that carries a cuff and a previously excised blood vessel segment within it (Figs. 31-33). The cuff is made of a nitinol wire mesh; and will thermally deform into a memory-shaped flared end which will become firmly anchored against the inner wall of the thoracic aorta. The cuff is desirably covered with a prosthetic material (such as Dacron and PTFE, etc.) to prevent any leaking of blood through the mesh cuff.

Continuous 5-0 Prolene is used for the anastomosis between the cuff and the grafts when the saphenous vein is the usual size (5 to 6 mm).

After the aortic puncture, the proximal end of the cuff vein graft is thermally deformed as it is released into the arterial lumen. The obturator is then retracted and the vein graft is slowly pulled back until the cuff is anchored and secured against the internal wall of the aorta via its deformed flared end. Once the cuff and the proximal end of the vein graft is internally anchored, the catheter and obturator are removed; and tissue adhesive (glue) is applied around the exit site of the bypass graft (between the graft and the adjacent outer wall of the aorta) so that any possibility of leakage of blood will be minimized and also to secure further the proximal anastomosis. The upper end of the vein graft is clamped to stop blood flow; and drugs are injected into the lower end to prevent it from going into spasm while the surgeon works on the coronary anastomosis.

**Exposure of the coronary arteries and creation of the distal anastomosis**

The sac covering the heart is cut, the thin coronary artery is under direct view. The patient is given calcium channel blockers and a beta blocker intravenously to slow the heart, which facilitate that the surgeons thread the stitches through the artery. The coronary artery vessels to be bypassed is identified and exposed after opening either hemithorax.

With a sharp knife, the surgeons cut into the coronary artery (arteriotomy). The arteriotomy is then increased to 8 to 12 mm with Pott's or reversed acute angle scissors. The internal diameter of the coronary artery is calibrated and the size recorded. The distal part of the graft that has been set aside is sewn to the coronary artery with the same fine sutures that are used in standard bypass operations. A continuous suture of 6-0 or 7-0 Prolene is begun in the heel of the vein graft with a narrow mattress stitch and continued to the proximal portion of the coronary artery. Approximately 1-mm bites are taken as the suture line is continued around one side to the distal end. At that point the suture line may be interrupted with one or more sutures. With smaller vessels interrupted sutures are easy to insert and less likely to constrict the anastomosis. With larger vessels (2.5 mm or greater) the suture line may be continued without interruption around the distal end. The other end of the original stitch is continued on the contralateral side, and the anastomosis is terminated at the midpoint of the arteriotomy.

Anastomotic patency is checked in both directions. A flush of clear solution through the needle may be of aid during the performance of the distal

anastomosis to keep the anastomotic area free of blood. Alternatively, the coronary artery and bypass vein grafts can be anastomosed by applying tissue adhesive (glue) between their adjacent outer walls, without using sutures, which facilitates and expedites the coronary anastomosis. when  
5 application of tissue adhesive make two structures bonded in a side-to-side fashion, a fenestration in a proper length is made between them by putting an incision extending from the lumen of vein graft to the lumen of the coronary artery with a knife inserted via the distal open end of the graft. After this, the open distal end of the vein graft is sewn as a blind end.

10 This procedure is repeated until all the blocked vessels to be revascularized are bypassed. After checking for bleeding, the surgeon closes the chest.

The present invention is not to be limited in scope nor restricted in form except by the claims appended hereto.

**TABLE 1:**  
**External and Lumen Diameter Measurements in Standard, Thin-Walled, and**  
**Super High-Flow Diagnostic Catheters**

<u>French</u>	<u>External Diameter</u>		<u>Standard</u> <u>(High Torque)</u>		<u>Thin-Walled</u> <u>(High Flow)</u>		<u>Super</u> <u>(High Flow)</u>	
	<u>inches</u>	<u>mm</u>	<u>inches</u>	<u>mm</u>	<u>inches</u>	<u>mm</u>	<u>inches</u>	<u>mm</u>
<u>Size</u>								
5	0.065	1.67	a	a	0.044	1.08	0.052	1.28
6	0.078	2.00	a	a	0.050	1.27	0.056	1.42
7	0.092	2.34	0.048	1.22	0.056	1.42	0.061	1.55
8	0.104	2.64	0.056	1.42	0.063	1.60	a	a
9	0.118	3.00	a	a	a	a	a	a

a No catheters made in this size/type.

What I claim is:

1. A catheter apparatus for creating a bypass on-demand between an unobstructed blood vessel and an obstructed blood vessel in-vivo using a graft segment as a conduit, said bypass catheter apparatus comprising:
  - a catheter suitable for introduction into and extension through the body in-vivo to a chosen site wherein an unobstructed blood vessel is in anatomic proximity to an obstruction lying within another blood vessel, said catheter being comprised of a hollow tube of fixed axial length having a discrete proximal end, a discrete distal end, and at least one internal lumen of predetermined diameter;
  - an obturator for on-demand introduction and passage through said catheter to a chosen site on the unobstructed blood vessel in-vivo, said obturator comprising
    - (1) a puncturing headpiece for puncture of and entry into the lumen of an unobstructed blood vessel;
    - (2) a perforating end tip on said puncturing headpiece to facilitate the perforation of a blood vessel wall at the chosen vascular site in-vivo
    - (3) an elongated shaft of fixed axial length integrated with said puncturing headpiece, said elongated shaft being configured for the carrying and transport of a graft conduit within said internal lumen of said catheter to the chosen site on the unobstructed blood vessel in-vivo; and
  - a thermally deformable cuff comprised of a shape-memory alloy for positioning over said elongated shaft adjacent to said puncturing headpiece of said obturator together with a graft segment
    - (i) wherein, prior to the perforation of the unobstructed blood vessel in-vivo by said puncturing headpiece of said obturator, at least a portion of said thermally deformable cuff in a first shaped configuration has been engaged and joined to one end of the graft segment then carried by said elongated shaft of said obturator,
    - (ii) and wherein, after the perforation of the unobstructed blood vessel in-vivo by said puncturing headpiece of said obturator, at least part of said engaged cuff is extended into the lumen of the unobstructed blood vessel, is thermally deformed in-situ into a memory-shaped second

configuration, and becomes attached via said thermal deformation to the interior of the unobstructed blood vessel, and

(iii) and whereby said cuff engaged end of the graft segment become secured to and placed in blood flow communication with the unobstructed blood vessel and serves as conduit means for bypassing an obstruction and restoring blood flow from the unobstructed blood vessel to the obstructed blood vessel.

2. The catheter apparatus as recited in claim 1 wherein said thermally deformable cuff is comprised of a nickel-titanium alloy.
3. The catheter apparatus as recited in claim 1 wherein said thermally deformable cuff is overlaid with a biocompatible coating.
4. The catheter apparatus as recited in claim 1 wherein said thermally deformable cuff comprises an open meshwork.
5. The catheter apparatus as recited in claim 1 wherein said thermally deformable cuff comprises a solid mass of material.
6. The catheter apparatus as recited in claim 1 wherein said obturator further comprises means for expansion and contraction of said puncturing headpiece on-demand.
7. The catheter apparatus as recited in claim 1 wherein said graft segment comprises a synthetic prosthetic channel section.
8. The catheter apparatus as recited in claim 1 wherein said graft segment comprises a previously excised blood vessel segment.
9. A catheterization method for creating a bypass on-demand between an unobstructed blood vessel and an obstructed blood vessel in-vivo using a graft segment as a conduit, said bypass catheterization method comprising the steps of:
  - providing a catheter suitable for introduction into and extension through the body in-vivo to a chosen site wherein an unobstructed blood

vessel is in anatomic proximity to an obstruction lying within another blood vessel, said catheter being comprised of a hollow tube of fixed axial length having a discrete proximal end, a discrete distal end, and at least one internal lumen of predetermined diameter, and

providing an obturator for on-demand introduction and passage through said catheter to a chosen site on the unobstructed blood vessel in-vivo, said obturator comprising

(1) a puncturing headpiece for puncture of and entry into the lumen of an unobstructed blood vessel,

(2) a perforating end tip of said puncturing headpiece to facilitate the perforation of a blood vessel wall at the chosen site in-vivo, and

(3) an elongated shaft of fixed axial length integrated with said puncturing headpiece, said elongated shaft being configured for the carrying and transport of a graft conduit within said internal lumen of said catheter to the chosen vascular site on the unobstructed blood vessel;

placing a graft segment on the elongated shaft adjacent to said puncturing headpiece of said obturator;

positioning a thermally deformable cuff comprised of a shape-memory alloy over said elongated shaft and one end of said graft segment lying adjacent to said puncturing headpiece of said obturator such that at least a portion of said thermally deformable cuff in a first configuration engages and is joined to the end of the said graft segment;

perforating the unobstructed blood vessel at the chosen site in-vivo using said puncturing headpiece of said obturator;

extending at least part of said engaged cuff into the lumen of the unobstructed blood vessel;

thermally deforming said extended cuff in-situ into a memory-shaped second configuration,

(i) whereby said engaged cuff becomes attached via said thermal deformation to the interior of the unobstructed blood vessel,

(ii) and whereby said deformed cuff and engaged graft segment become secured to and placed in blood flow communication with the unobstructed blood vessel; and

joining the other end of the secured graft segment to the obstructed blood vessel at a chosen site distal to the obstruction, said joined graft

serving as conduit for means for bypassing the obstruction and restoring blood flow from the unobstructed blood vessel to the obstructed blood vessel.

10. The catheterization method as recited in claim 9 wherein the bypass conduit is created between an unobstructed artery and an obstructed artery.

11. The catheterization method as recited in claim 9 wherein the bypass conduit is created between an unobstructed vein and an obstructed vein.

12. The catheterization method as recited in claim 9 wherein the bypass conduit is created between an artery and a vein.

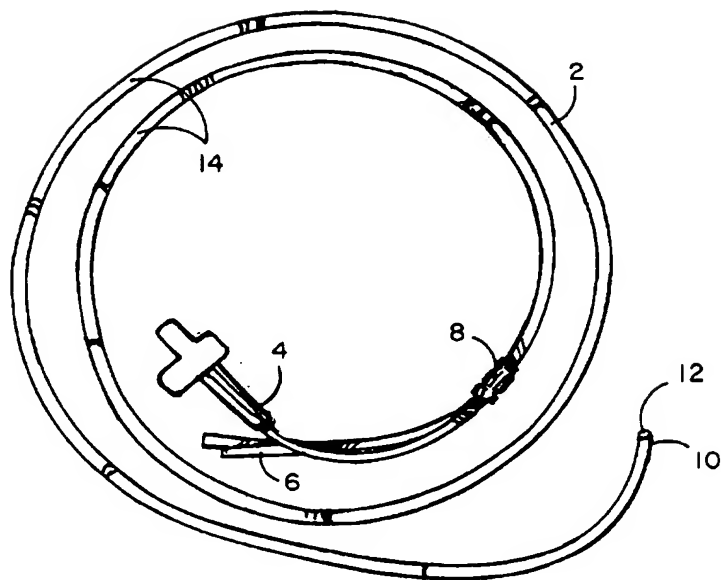


FIG. 1

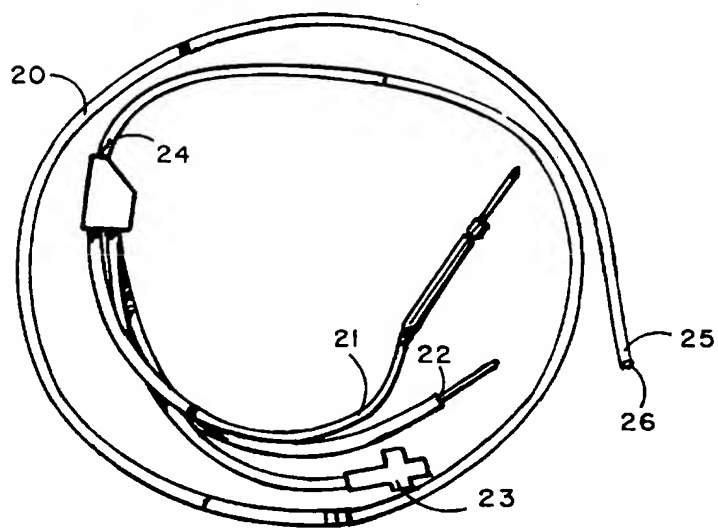


FIG. 2



FIG. 3A



FIG. 3B

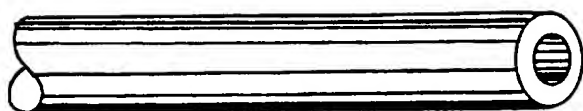


FIG. 4A

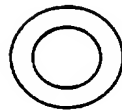


FIG. 4B

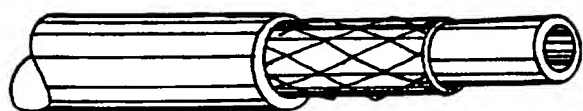


FIG. 5A

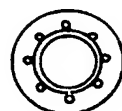


FIG. 5B

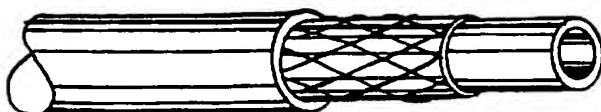


FIG. 6A

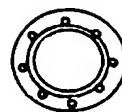


FIG. 6B

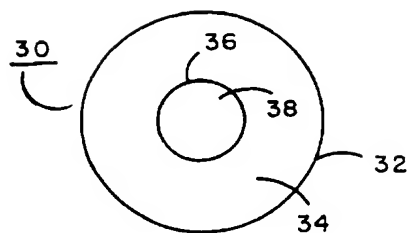


FIG. 7A

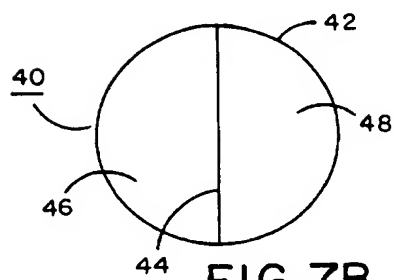


FIG. 7B

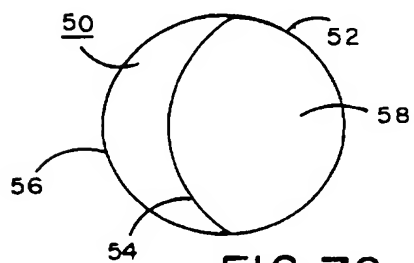


FIG. 7C

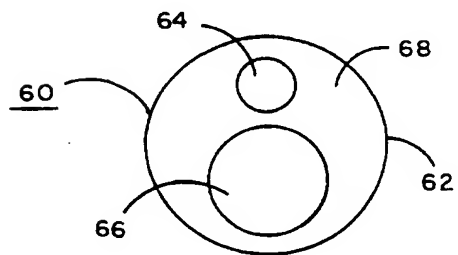


FIG. 7D

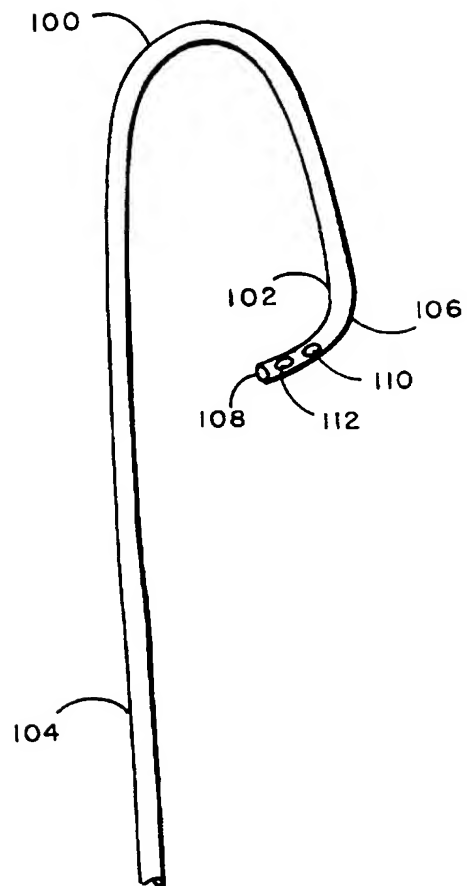


FIG. 8

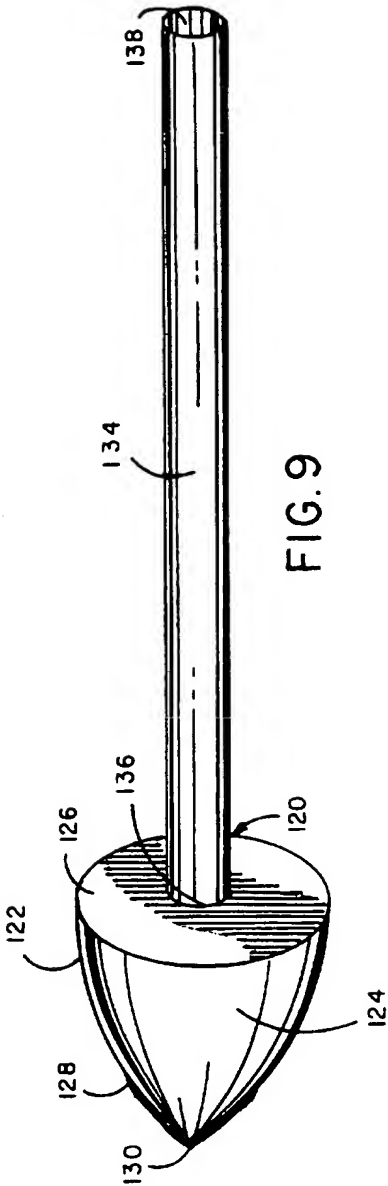


FIG. 9

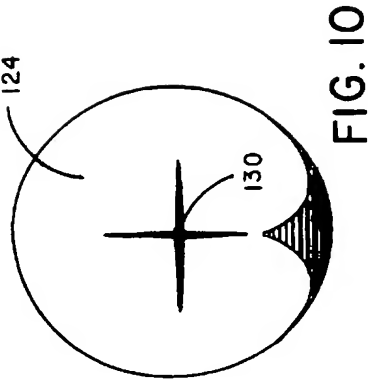
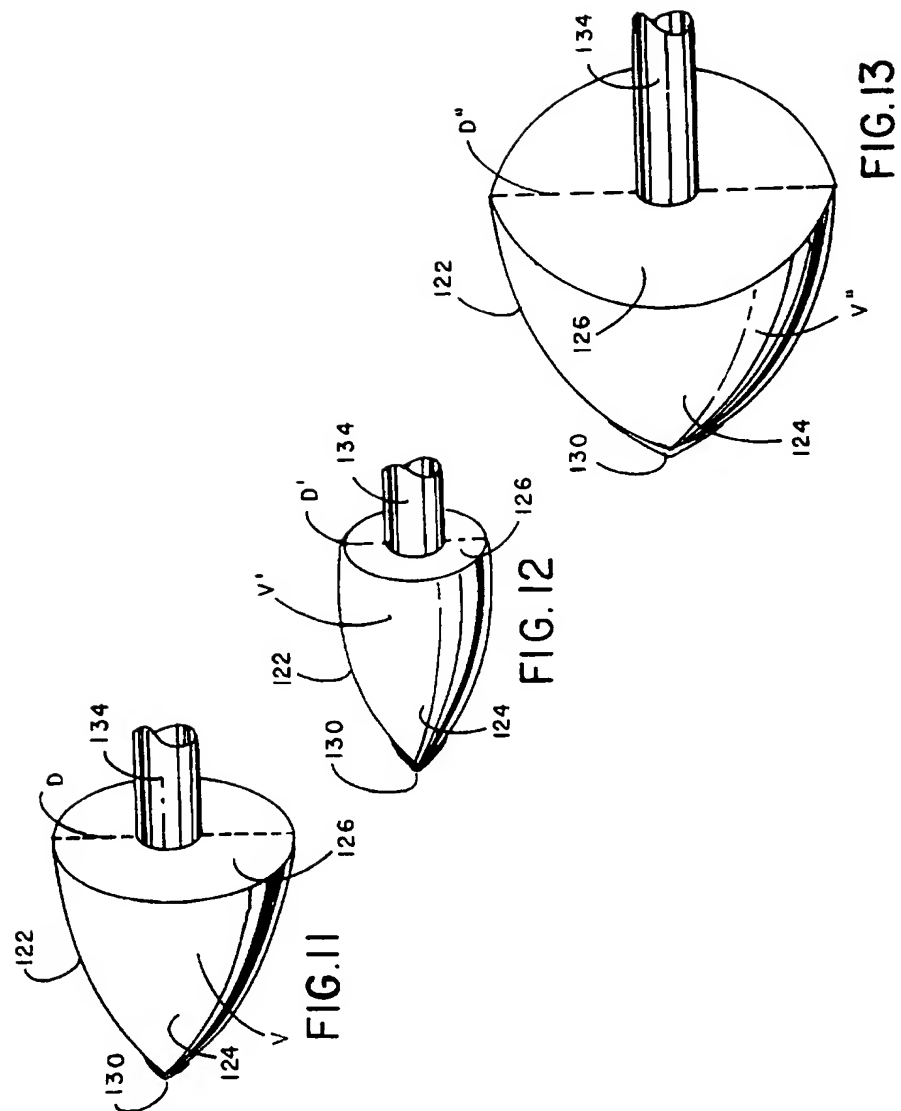


FIG. 10



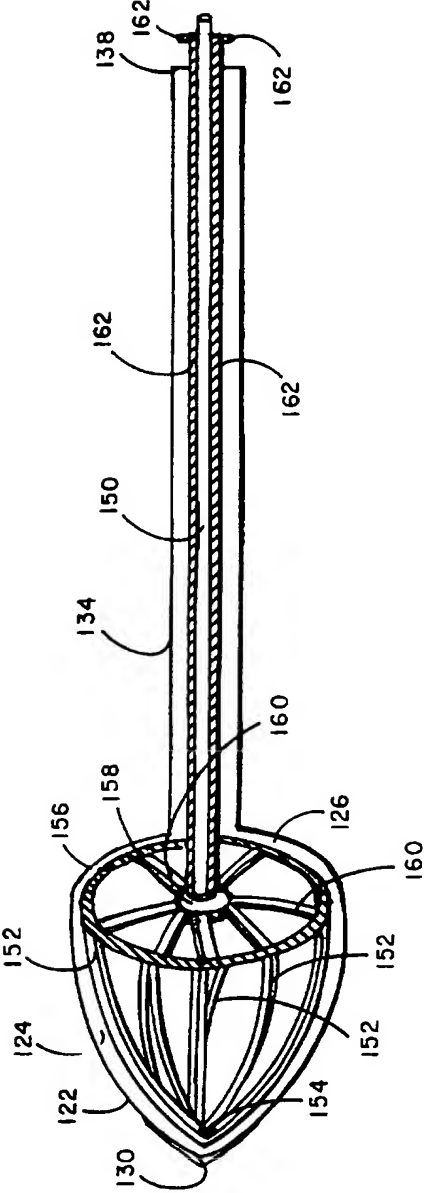


FIG. 14

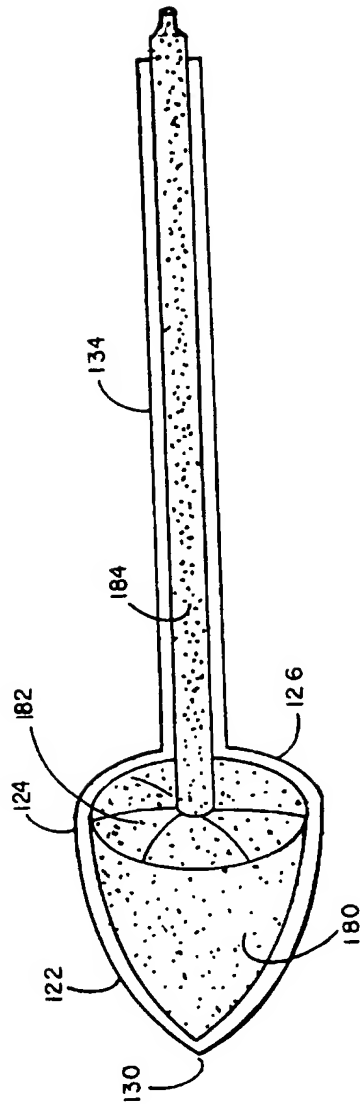


FIG. 15

9/26

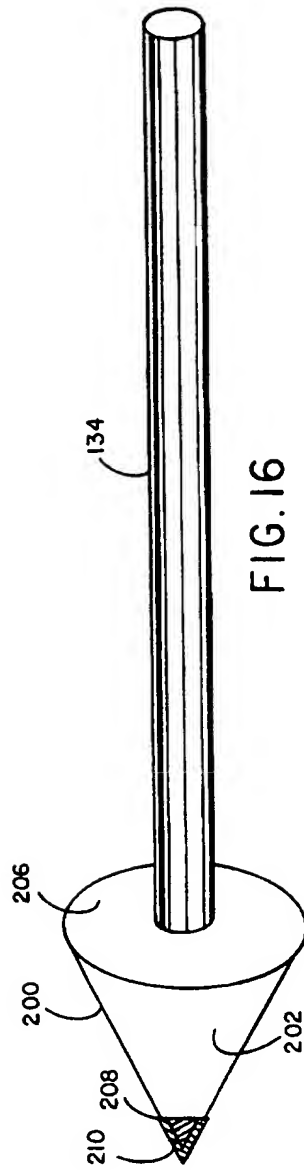


FIG. 16

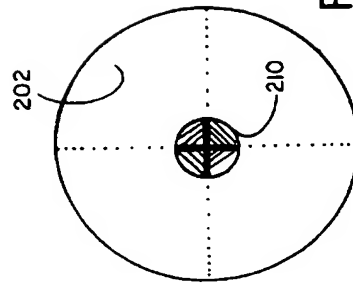


FIG. 17

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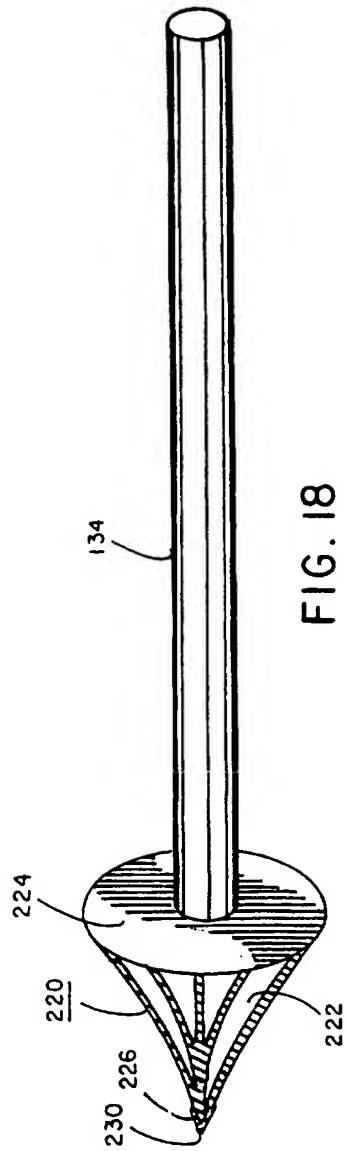


FIG. 18

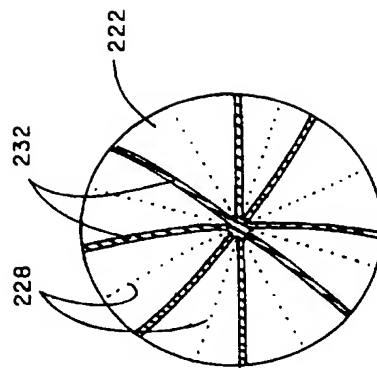


FIG. 19

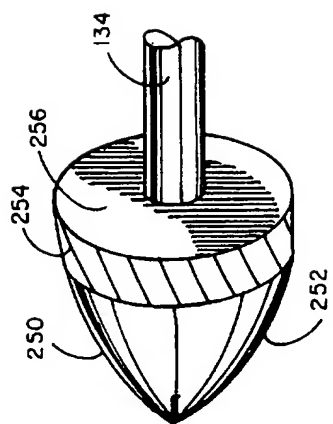


FIG. 20

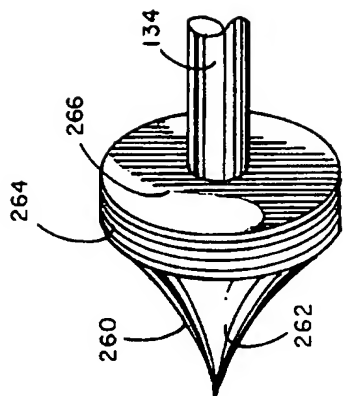


FIG. 21

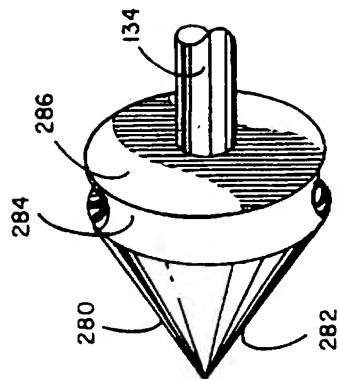
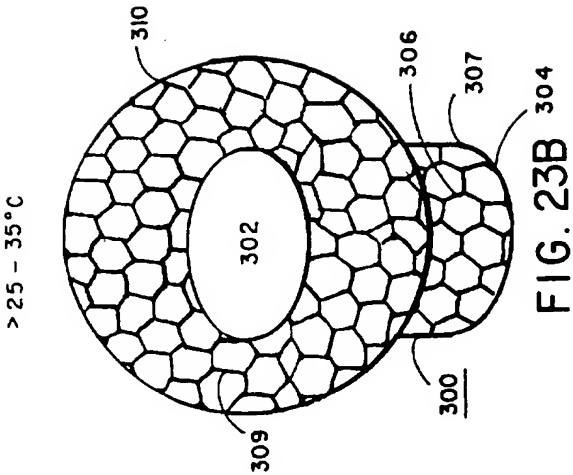
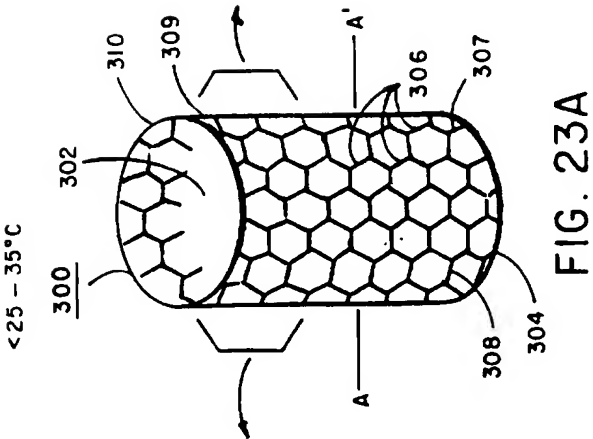
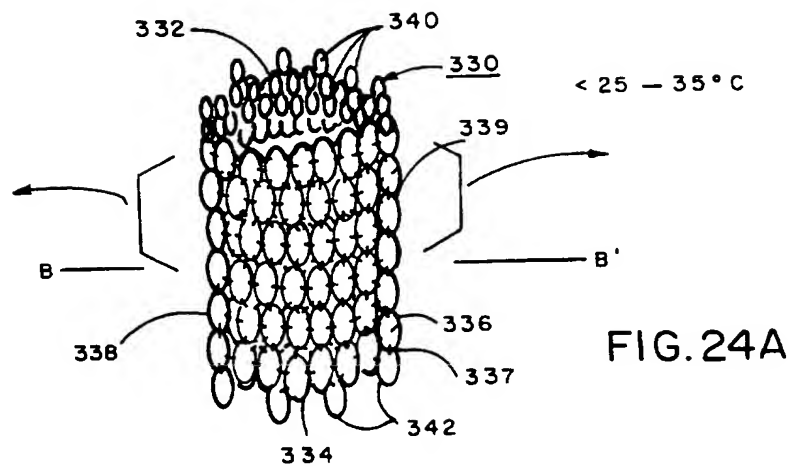
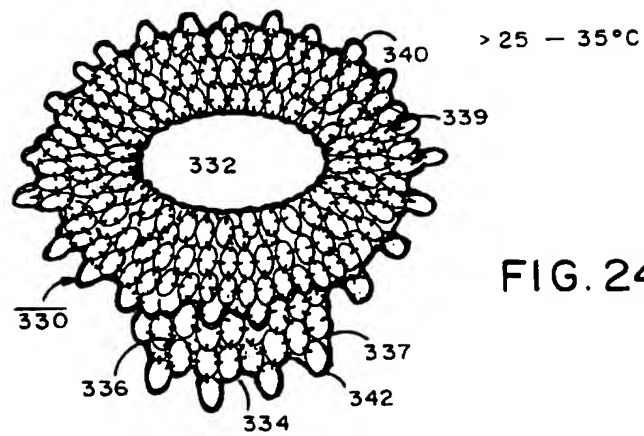
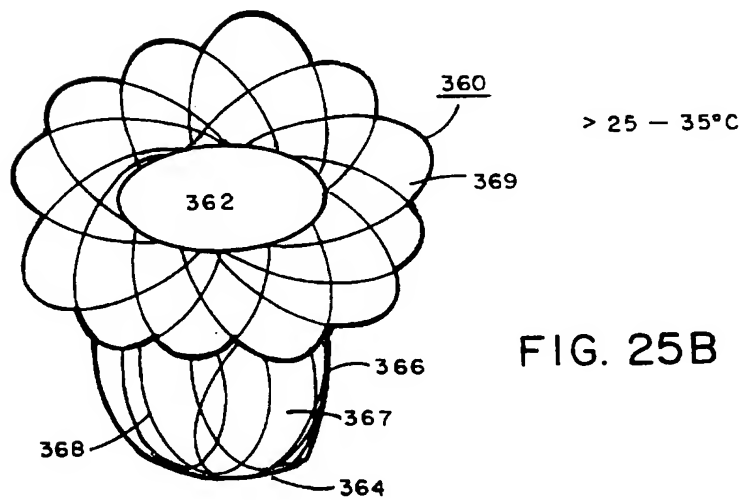
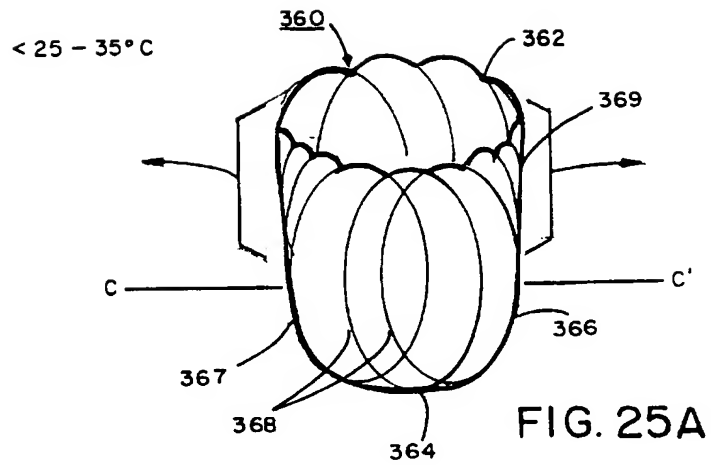
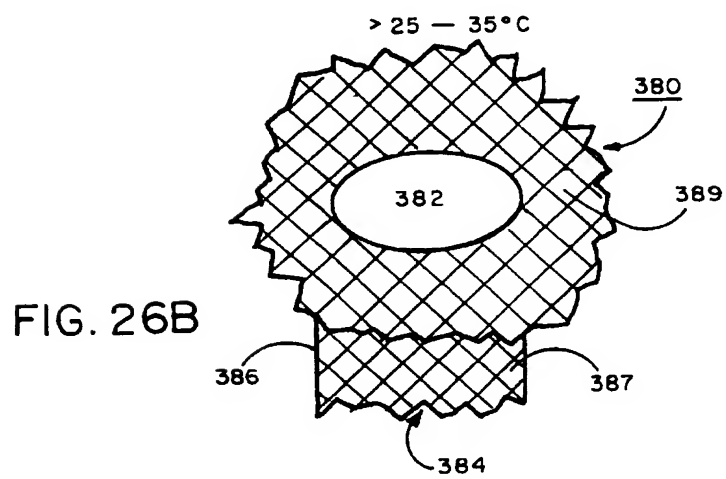
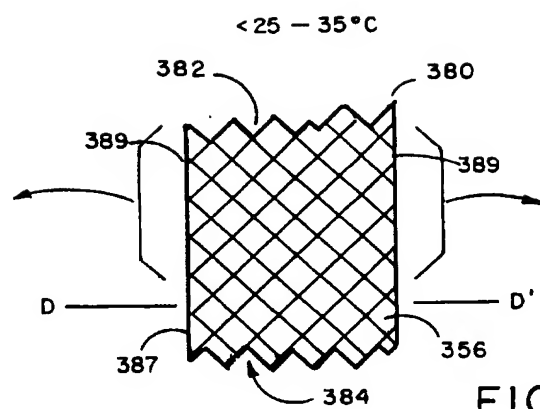


FIG. 22









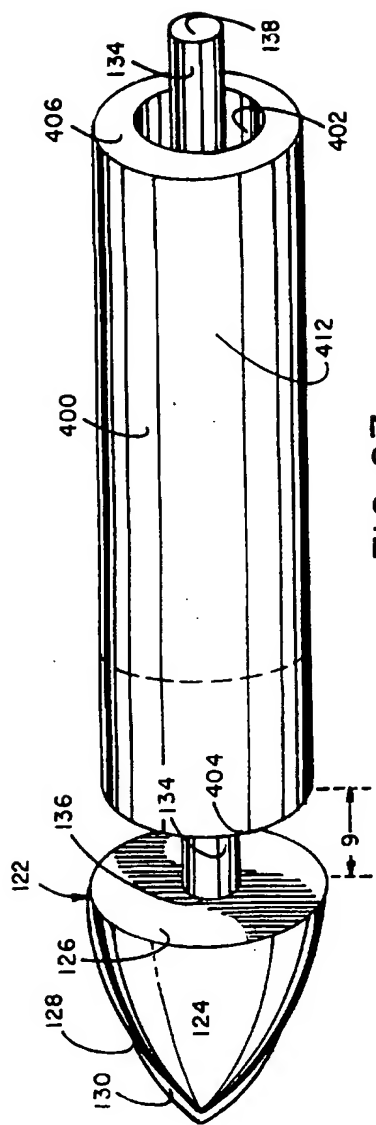


FIG. 27

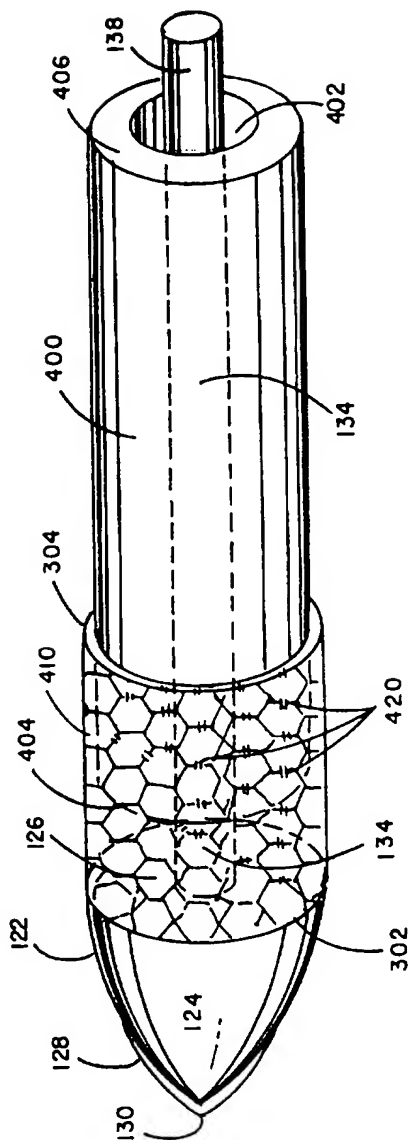


FIG. 28

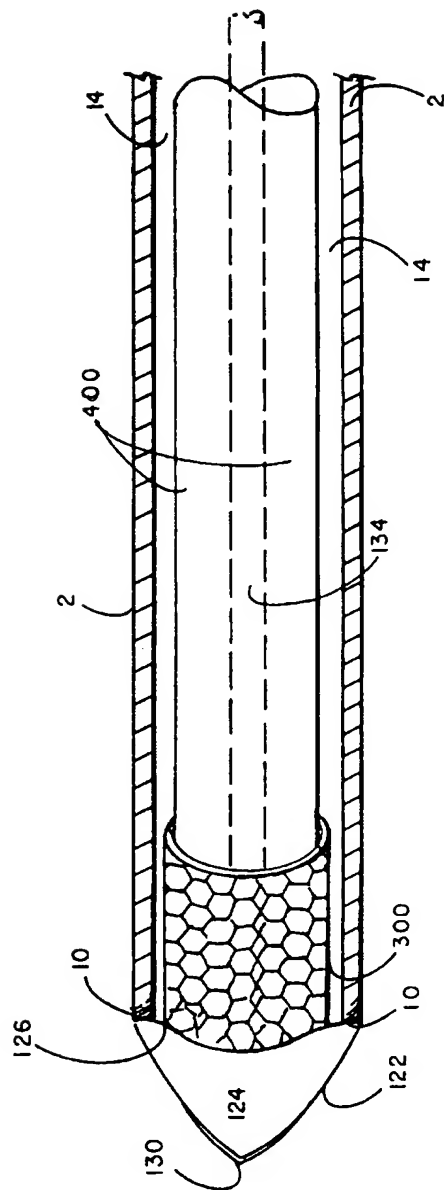


FIG. 29

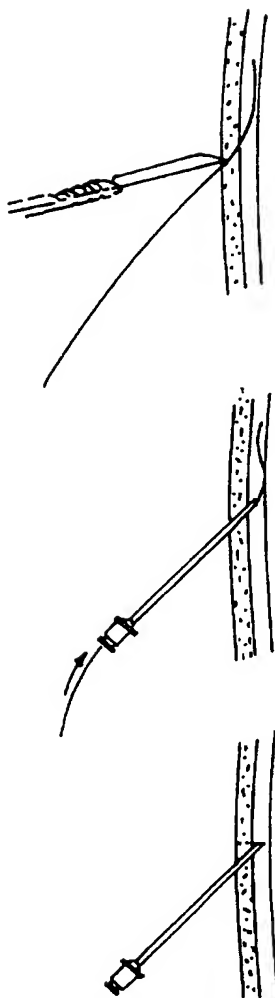


FIG. 30C

FIG. 30B

FIG. 30A

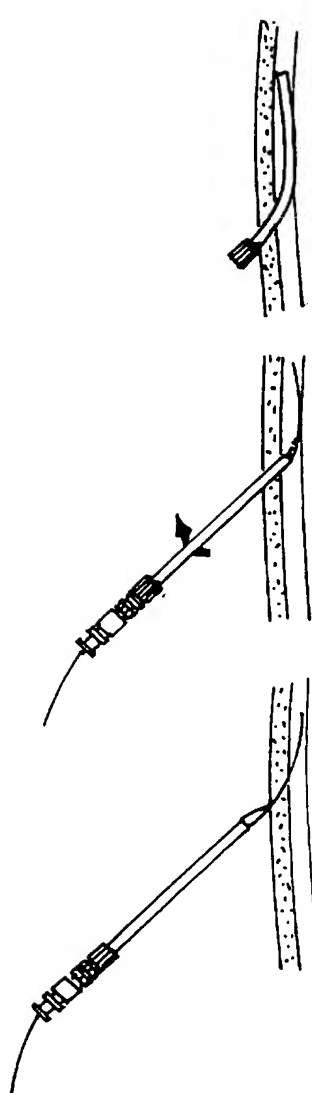
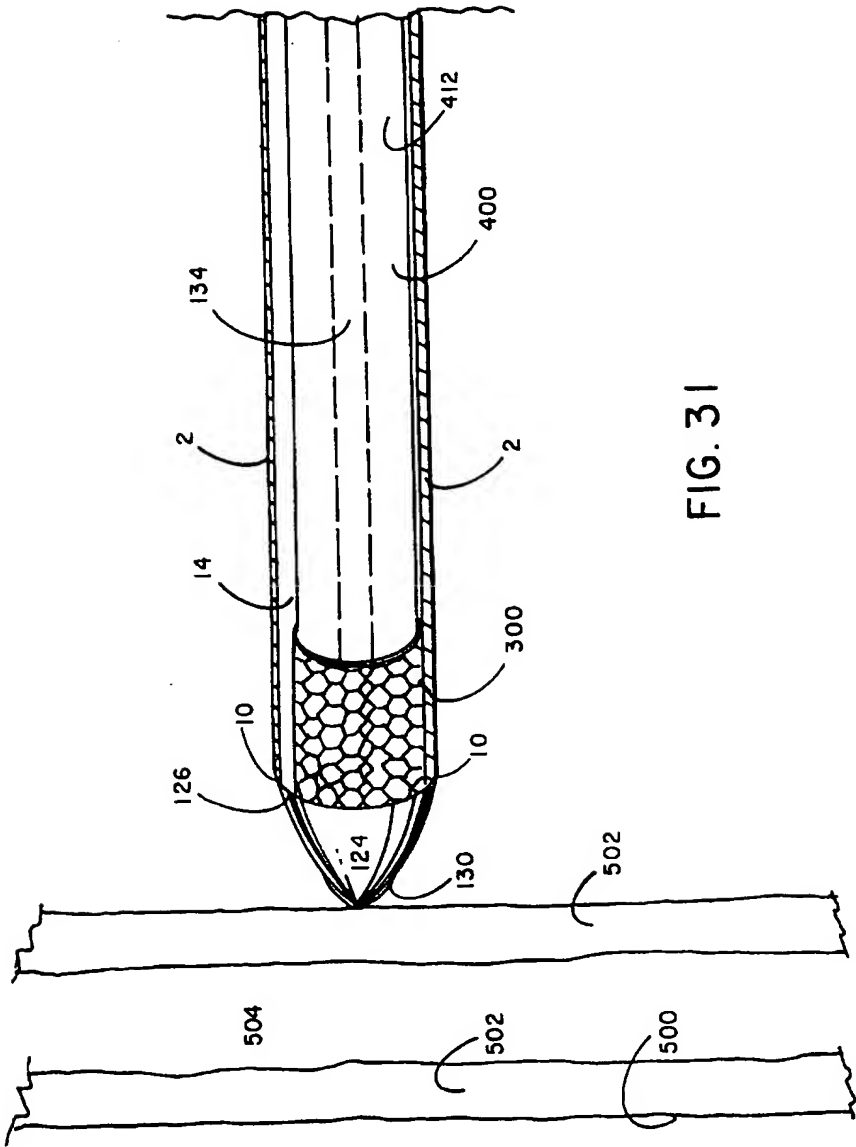


FIG. 30F

FIG. 30E

FIG. 30D



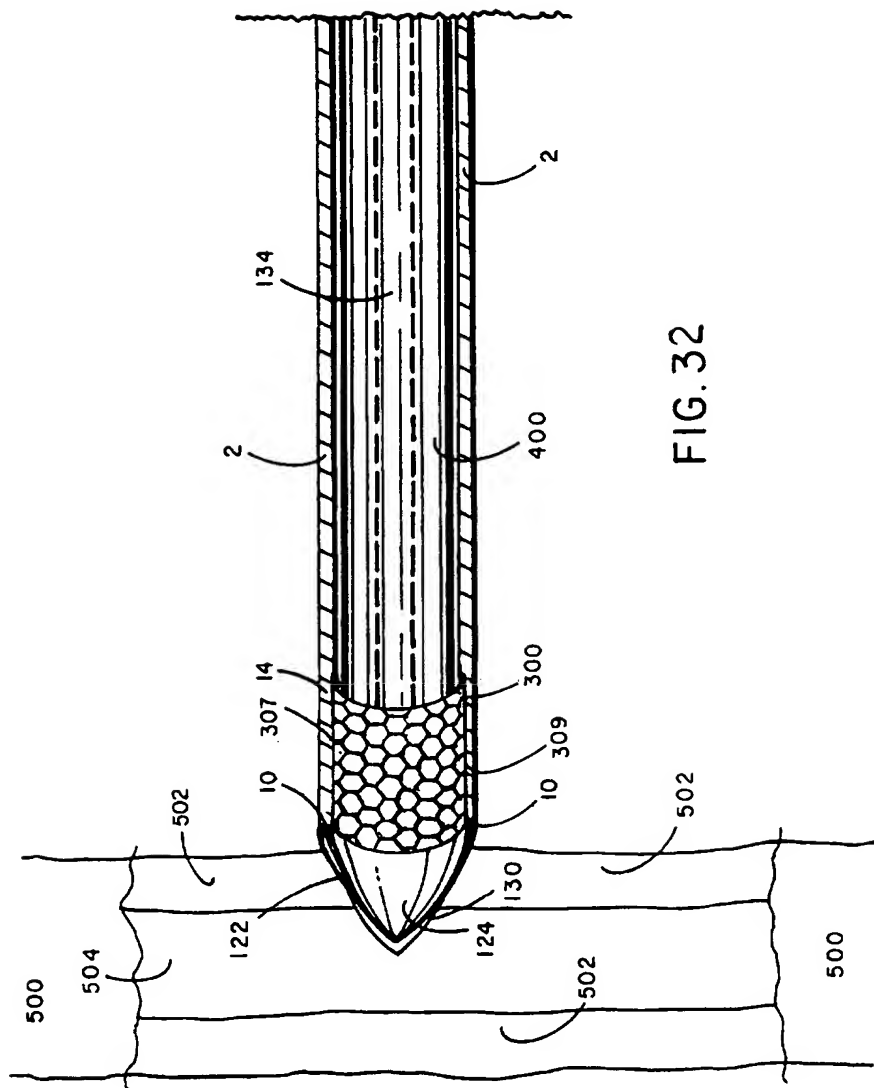


FIG. 32

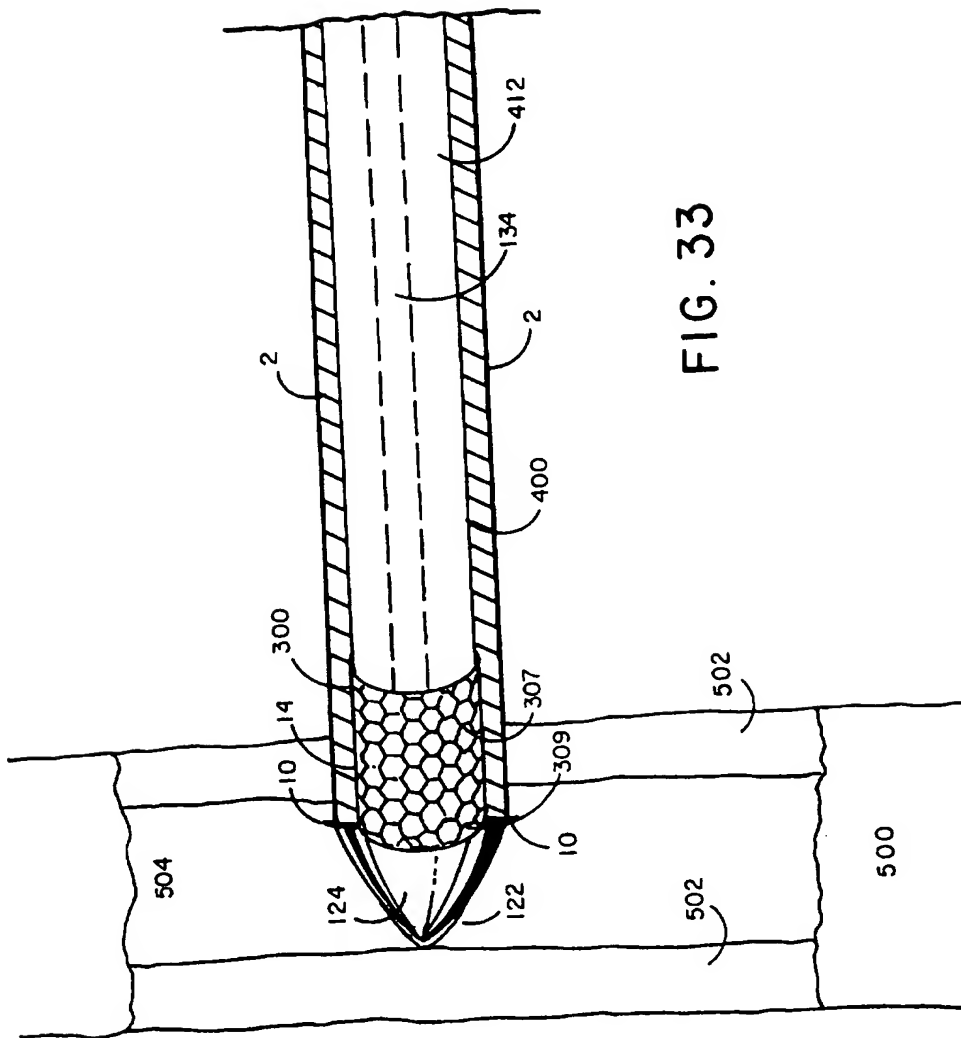
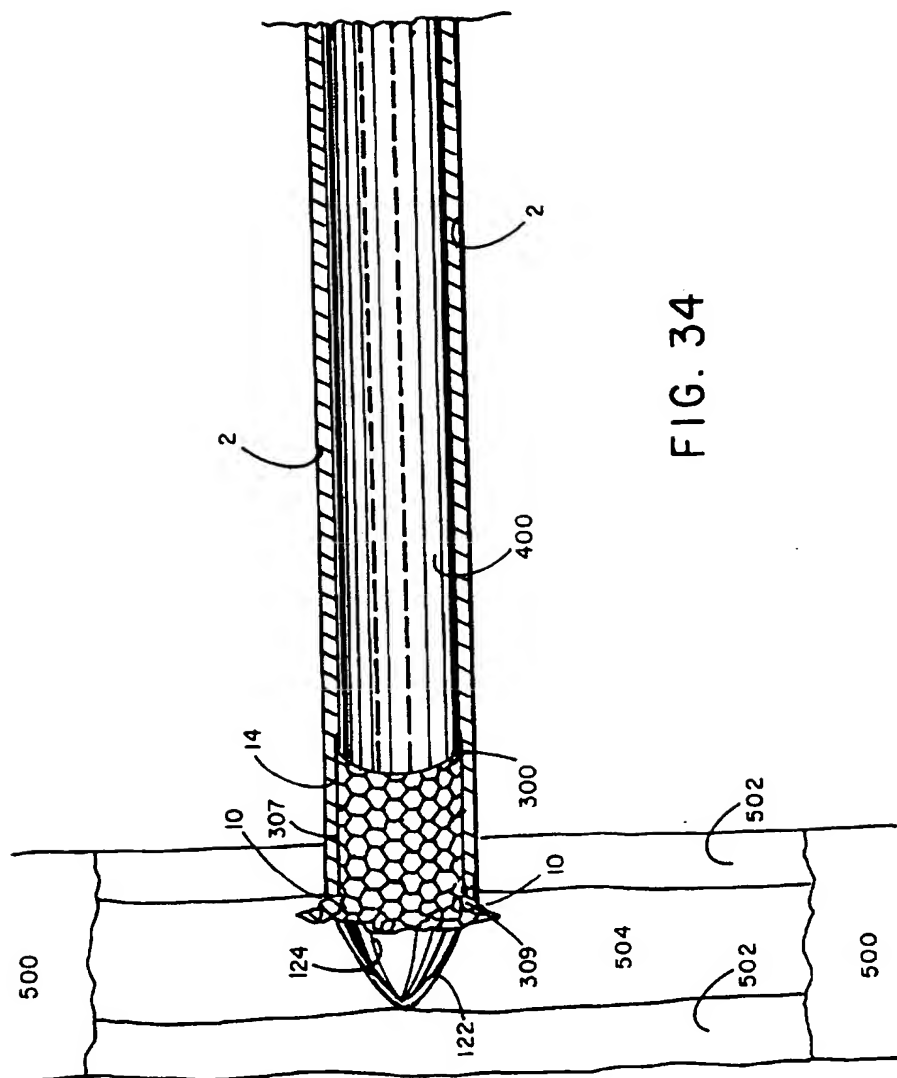


FIG. 33



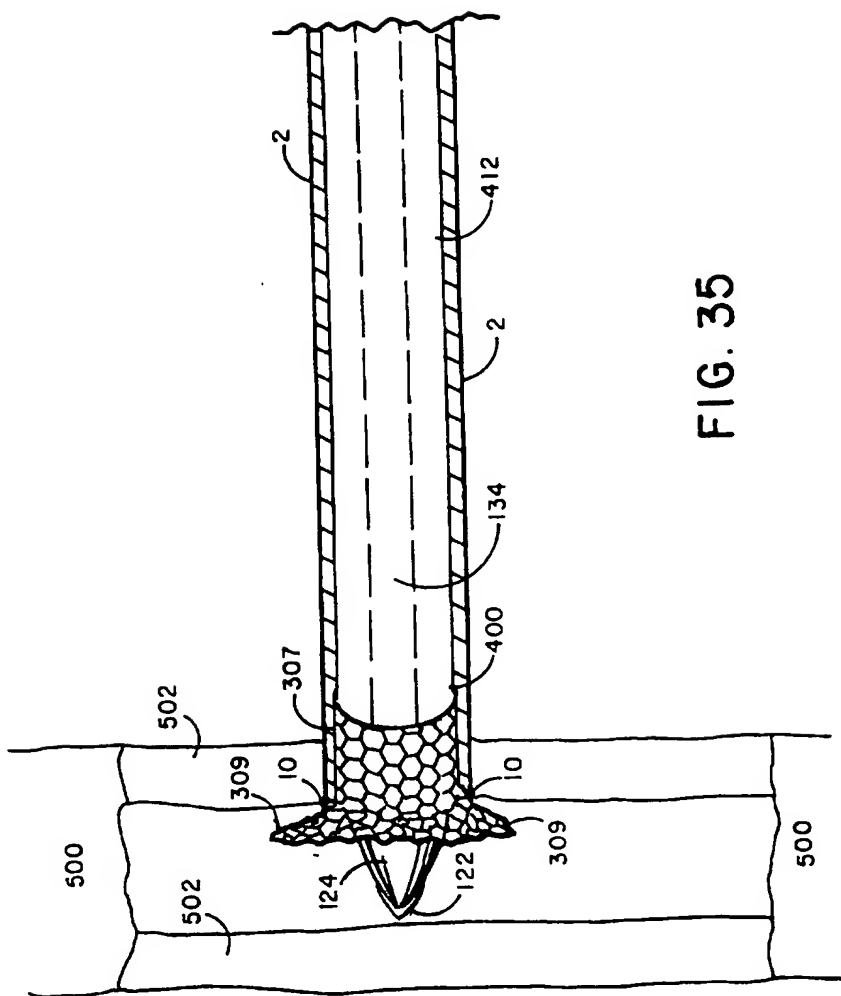


FIG. 35

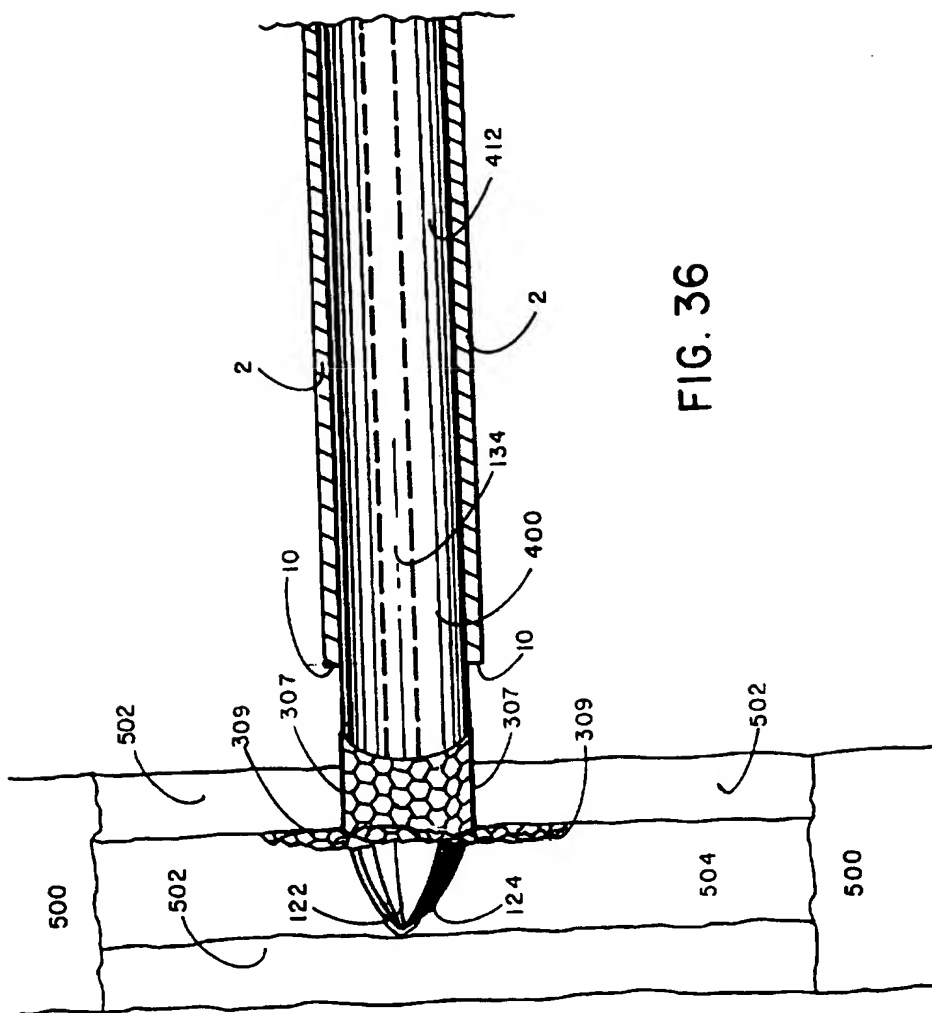


FIG. 36

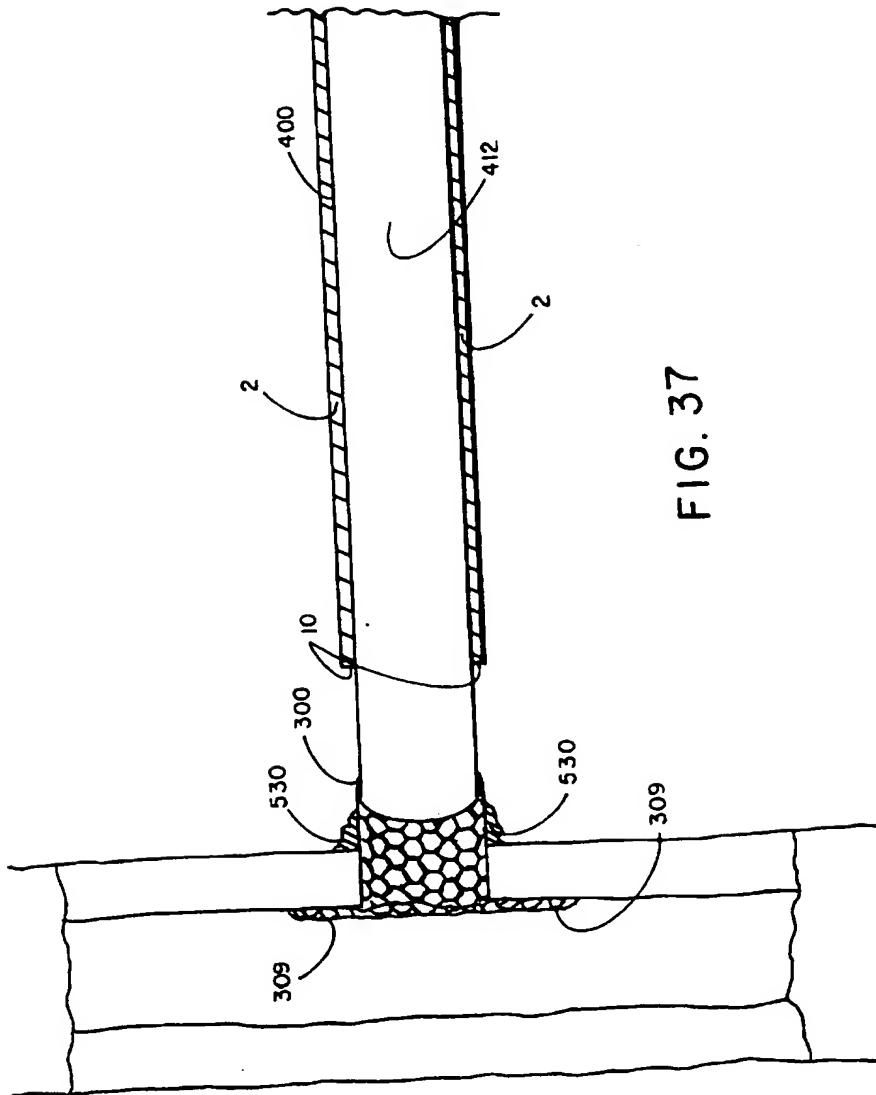
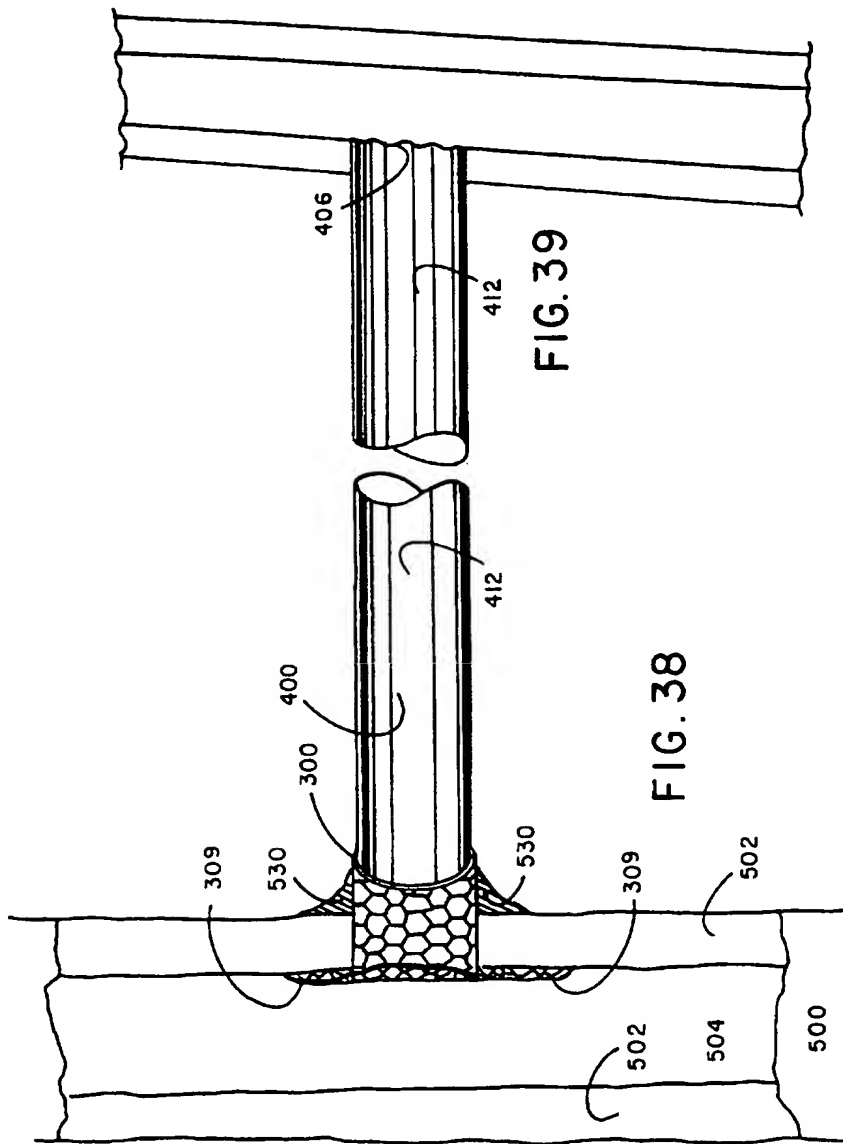


FIG. 37



## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US97/14265

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61F 11/00

US CL : 606/108

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/164; 606/108, 159, 184, 185, 192, 195, 198; 623/ 1, 12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

Search Terms: (catheter or introduc?) and (obturator or dilator or punct?) and (SMA or shape memory alloy# or thermal## expan?)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,769,031 A (McGOUGH et al) 06 September 1988, entire document.	1-12
Y	US 5,540,713 A (SCHNEPP-PESCH et al) 30 July 1996, entire document.	1-5, 7-12.
Y	US 5,316,023 A (PALMAZ et al) 31 May 1994, Figs. 1-10.	1-5, 7-12
Y	US 5,431,676 A (DUBRUL et al) 11 July 1995, col. 3 line 35 to col. 12 line 50, and Figs. 1-20.	6

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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<p>(51) International Patent Classification 6 :  <b>A61B 17/115</b></p>	<p><b>A1</b></p>	<p>(11) International Publication Number: <b>WO 97/40754</b>  (43) International Publication Date: 6 November 1997 (06.11.97)</p>
<p>(21) International Application Number: PCT/DK96/00197  (22) International Filing Date: 30 April 1996 (30.04.96)  (71) Applicants (for all designated States except US): OTICON A/S [DK/DK]; Strandvejen 58, DK-2900 Hellerup (DK). BERNAFON AG [CH/CH]; Morgenstrasse 131, CH-3018 Berne (CH).  (71)(72) Applicant and Inventor: RYGAARD, Jørgen, A. [DK/DK]; Parkovsvej 40, DK-2820 Gentofte (DK).  (74) Agent: BUDDE, SCHOU &amp; CO. A/S; Vestergade 31, DK-1456 København K (DK).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b>  <i>With international search report.</i></p>

In a method of establishing an end-to-side anastomosis by using an instrument (501) with a passage (502D) for a bypass vessel, terminated by a circumferential anvil (502A, 503B), about which the end of the bypass vessel may be everted and then inserted through an anastomosis opening in a second vessel, such as a coronary artery, after which the tissue edges to be joined are first clamped together by clamping slides (505) and then stapled together by stapling plungers (506) so as to interconnect the two vessels, the main novel feature is that the stapling plungers (506) are arranged to move at an angle to the passage (502D) instead of parallel to it. With this arrangement, it is possible to use a greater number of staples than has been possible in previous related methods. Preferably also, the instrument is adapted to be divided lengthwise of the passage (502D).

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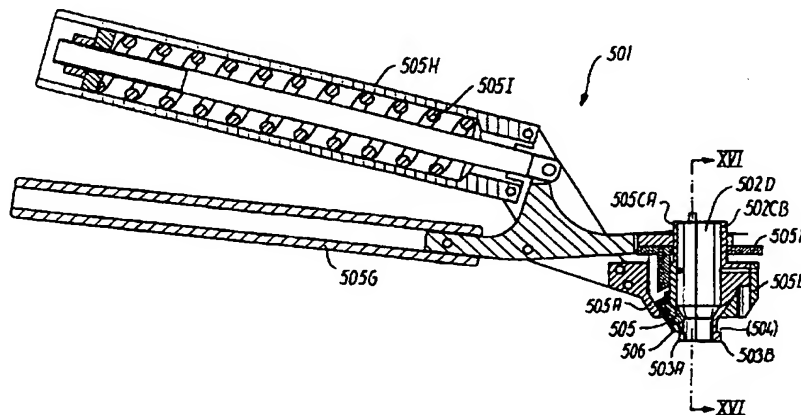
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>A61B 17/115</b>	<b>A1</b>	(11) International Publication Number: <b>WO 97/40754</b> (43) International Publication Date: 6 November 1997 (06.11.97)
(21) International Application Number: PCT/DK96/00197 (22) International Filing Date: 30 April 1996 (30.04.96) (71) Applicant (for all designated States except US): OTICON A/S [DK/DK]; Strandvejen 58, DK-2900 Hellerup (DK). (71)(72) Applicant and Inventor: RYGAARD, Jørgen, A. [DK/DK]; Parkovsvej 40, DK-2820 Gentofte (DK). (74) Agent: BUDDE, SCHOU & CO. A/S; Vestergade 31, DK-1456 København K (DK).		(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  Published With international search report.

(54) Title: METHOD AND ANASTOMOTIC INSTRUMENT FOR USE WHEN PERFORMING AN END-TO-SIDE ANASTOMOSIS



(57) Abstract

In a method of establishing an end-to-side anastomosis by using an instrument (501) with a passage (502D) for a bypass vessel, terminated by a circumferential anvil (502A, 503B), about which the end of the bypass vessel may be everted and then inserted through an anastomosis opening in a second vessel, such as a coronary artery, after which the tissue edges to be joined are first clamped together by clamping slides (505) and then stapled together by stapling plungers (506) so as to interconnect the two vessels, the main novel feature is that the stapling plungers (506) are arranged to move at an angle to the passage (502D) instead of parallel to it. With this arrangement, it is possible to use a greater number of staples than has been possible in previous related methods. Preferably also, the instrument is adapted to be divided lengthwise of the passage (502D).

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METHOD AND ANASTOMOTIC INSTRUMENT FOR USE WHEN PERFORMING  
AN END-TO-SIDE ANASTOMOSIS

TECHNICAL FIELD

5

The present invention relates to a method of the kind set forth in the preamble of claim 1.

BACKGROUND ART

10

A method of this kind is described in the international application PCT/DK95/00430. In this previous method, the stapling plungers as well as the associated clamping members were adapted to move in directions substantially parallel to the passage, in which the graft vessel was placed in readiness for establishing an end-to-side anastomosis with e.g. a coronary artery. With such an arrangement, the number of staples as well as their mutual closeness were limited by the purely mechanical need for guiding the stapling plungers in their operative movement, with the result that in the "seam" connecting the two vessels, there could be substantial distances between adjacent staples.

25

DISCLOSURE OF THE INVENTION

It is the object of the present invention to provide a method of the kind referred to above, with which it is possible to use the instrument for establishing anastomoses with a greater number of staples and with smaller distances between adjacent staples than has been possible with the previously known method referred to above. This object is achieved by proceeding as set forth

30

in the characterizing clause of claim 1. In this manner, the guideways for the stapling plungers will mostly be situated at a greater "radius" than the staple-bending recesses, so that there is ample space for forming these  
5 guideways in a greater number than previously, to converge at very small mutual distances at the staple-bending recesses in the anvil.

The present invention also relates to an anastomotic  
10 instrument for carrying out the method according to the invention, and this instrument is characterized by the features set forth in claim 4.

Advantageous embodiments of the method and the anastomotic  
15 instrument according to the invention, the effects of which - beyond what is self-evident - are explained in the following detailed part of the present description, are set forth in claims 2, 3 and 5-7, respectively.

20 BRIEF DESCRIPTION OF THE DRAWINGS

In the following detailed part of the present description, the invention will be explained in more detail with reference to the exemplary embodiments of an anastomotic  
25 instrument according to the invention shown in the drawings, in which

Figures 1-8 show the process of performing an end-to-side anastomosis using an anastomotic instrument  
30 according to the invention subject of the application PCT/DK95/00430 referred to initially, Figures 1-7 being drawn in a highly simplified manner for ease of understanding,

Figures 9-11 in perspective and with certain parts cut away show a practical embodiment of an anastomotic instrument according to the present invention with the various possible relative positions of the relatively movable parts,

Figures 12-14 are side views of a staple-pusher set consisting of a stapling plunger, a clamping slide and their common operating slide in positions corresponding to those shown in Figure 9-11, respectively.

Figure 15 is a sectional side view of the complete instrument,

Figure 16 is a sectional view taken along the line XVI-XVI in Figure 15,

Figures 17-19 show a core member with associated anvil tube as viewed from the rear, side and front, respectively, and

Figures 20-22 show a housing likewise as viewed from the rear, side and front, respectively.

Please note that the "front end" of the instrument is the end comprising the part in operation being in contact with the anastomosis being established, in this case the anvil 503A, 503B.

30

#### DESCRIPTION OF THE PREFERRED EMBODIMENTS

As mentioned above, the embodiment shown in Figures 1-8 of the anastomosis instrument according to the invention

subject of the application PCT/DK95/00430 constitutes a simplified version with the primary purpose of explaining the invention; this does not, however, preclude the possibility of using this embodiment in actual practice.

5

Thus, Figure 1 shows an anastomosis instrument 1 consisting of three main components that are movable relative to each other in the longitudinal direction, i.e. in the direction shown as the vertical direction in Figure 1:

10

- an anvil tube 2,
- a clamping tube 5, and
- a set of stapling plungers 6.

15

On its lower end, the anvil tube 2 carries an anvil 3, the upper side of which is provided with a number of staple-bending recesses 4 adapted to cooperate with and bend an equal number of staples 7, in the situation shown in Figure 1 being temporarily held lightly in an equal number of staple-holding recesses 8 formed in the lower ends of the stapling plungers 6.

20

Figure 2 shows the situation, in which the instrument is made ready for use by the operating surgeon. As mentioned initially, the anastomosis instrument shown is primarily developed for use when performing coronary bypass operations, and to this end, a bypass vessel 9 - that may be a vein taken from some other part of the patient's body - has been inserted in the anvil tube with its lower end everted about the anvil 3 and with its end region 10 covering the staple-bending recesses 4 in the upper surface of the anvil 3. At this point it should be noted that the bypass vessel 9 may have a considerably larger circumference than the inside of the anvil tube 2,

25

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consequently lying more or less folded in the longitudinal direction in the latter, for which reason the action of everting its end region 10 about the anvil 3 does not necessarily entail undue stretching of the bypass vessel 9.

Figure 3 shows the instrument having been made ready as shown in Figure 2 inserted in an opening in a coronary artery 11, said opening having an edge region 12 which, due to the elasticity of the tissue of the coronary artery 11, will embrace the anvil tube 2 in a location close to the anvil 3. The opening in the coronary artery 11 may e.g. have been formed according to the method described in the international application with publication No. WO 95/17127 with the title "Method and instrument for establishing the receiving side of a coronary artery bypass graft".

As soon as the operating surgeon in the situation shown in Figure 3 has ascertained that the edge region 12 embraces the anvil tube 2 closely on all sides, he or she will proceed to the situation shown in Figure 4, in which the clamping tube 5 has been moved towards the anvil 3 so as to clamp the edge region 12 on the coronary artery 11 and the end region 10 on the bypass vessel 9 firmly together in readiness for the next step shown in Figure 5, in which the stapling plungers 6 have been moved downwardly so as to cause the staples 7 to penetrate the edge region 12 and the end region 10 and engage the staple-bending recesses 4, by which they will be bent inwards in a tangential direction in a similar manner to what is known from both surgical staplers and ordinary office staplers.

## 6

In the situation shown in Figure 6, the clamping tube 5 together with the stapling plungers 6 have been moved outwardly and away from the staples 7, the staple-holding recesses 8 due to their light holding action having let go of the staples 7, the latter also having been anchored in the end region 10 by their bent ends.

Figure 7 shows the situation, in which the operation of removing the anastomosis instrument 1 from the coronary artery 11 and its anastomosis with the bypass vessel 9 has begun. As will be seen from Figures 6 and 7, the circumferential pocket formed by the eversion of the lower end of the bypass vessel 9 will now open and allow the anvil 3 to be removed by luxation, Figure 8 showing the situation after such removal, resulting in a finished anastomosis of the intima-to-intima type considered most desirable for this type of operation.

The three main components of the anastomosis instrument 1 referred to above, i.e. the anvil tube 2, the clamping tube 5 and the set of stapling plungers 6, will, of course, have to be connected to some kind of operating members to enable the operating surgeon and his or her assistants to carry out the steps shown in Figures 1-8. Theoretically, these operating members could consist of three tubes (not shown), viz.

- a relatively long holding tube in continuation of the anvil tube 2,
- a somewhat shorter clamping tube in continuation of the clamping tube 5, and
- an even shorter stapling tube, to which the stapling plungers 6 are connected.

As is well-known, however, coronary bypass operations,

especially according to the method subject to the international application No. WO 95/17127 entitled "Method and instrument for establishing the receiving site of a coronary artery bypass graft", should be carried out as rapidly as possible, and for this reason, the "theoretical" embodiment shown in Figures 1-7 is too cumbersome to work with to ensure a sufficiently rapid operating procedure. As mentioned above, Figures 9-22 illustrate an embodiment of an anastomosis instrument according to the present invention, that is highly suitable for creating an end-to-side anastomosis in a very short time.

In Figures 9-22, those of the components functionally corresponding to components shown in Figures 1-7 have been given the same reference numbers with 500 added, whereas components not having "opposite numbers" in Figures 1-7 have been given the reference numbers of the components, with which they are most closely related, with the addition of a capital letter.

As shown in Figure 9, the anastomosis instrument 501 comprises a number of parts functionally related to parts of the instrument shown in Figures 1-7, viz.:

- an anvil tube 502A, 502B,
- an anvil 503A, 503B,
- a set of clamping slides 505, slidable in
- a clamping-slide housing 505A, 505B, and
- a set of stapling plungers 506 slidable in said clamping slides 505.

Although the basic functions of these parts are the same as the basic functions of related parts in the embodiment of Figures 1-7, the arrangement differs somewhat from

that of the latter, as will be evident from the following.

Thus, the anvil tube 502A, 502B of Figure 9 is an extension of a core member 502CA, 502CB, cf. also Figure 15, a central passage 502D extending all the way through both the core member 502CA, 502CB and the anvil tube 502A, 502B so as to make it possible to place a bypass vessel in the passage in the same manner as shown in Figure 2, showing a bypass vessel 9 placed in the anvil tube 2.

The rear face of the anvil 503A, 503B, facing upwardly in Figure 9, is provided with a number of staple-bending recesses 504 substantially evenly distributed about the anvil and each adapted to co-operate with a respective one of the stapling plungers 506.

The clamping slides 505 are adapted to slide in a direction making an angle of substantially 30° with the longitudinal axis of the passage 502D, being guided for such movement by guideways formed in the inside of the slide housing 505A, 505B and in the outside of the core member 502CA, 502CB.

Similarly, each of the stapling plungers 506 is adapted to slide in substantially the same direction in a guideway in a respective one of the clamping slides 505. Both the clamping slides 505 and the stapling plungers 506 are provided with short operating studs 505C and 506C, respectively, for co-operation with angular operating slots 505D formed in operating slides 505E adapted to slide in guideways formed in the inside of the slide housing 505A, 505B and in the outside of the core member 502CA, 502CB in a direction substantially parallel to the longitudinal

axis of the passage 502D.

5 All the operating slides 505E are connected to a common operating head 505F, the latter in turn being connected to one arm 505G of a pair of tongs 505G, 505H adapted to be operated manually by the surgeon, the other arm 505H being connected to the core member 502A, 502B and the clamping-slide housing 505A, 505B.

10 When an anastomosis is to be established according to the principles explained above with reference to Figures 1-8, the first step is, with the mutually movable parts in the positions shown in Figures 9 and 12 and with the stapling plungers 506 "loaded" with staples (not shown),  
15 to place a bypass vessel in the passage 502D and evert its forward (lower) end about the anvil 503A, 503B in the manner shown in Figure 2. The next step is to insert the anvil 503A, 503B with the everted end of the bypass vessel into an opening formed in the side of, say, a coronary artery in the manner shown in Figure 3. These two  
20 steps are suitably carried out using the pair of tongs 505G, 505H as a "handle".

25 When the surgeon has ascertained that the bypass vessel is in the correct position relative to the artery, she or he will press the arm 505G towards the arm 505H, thus causing the common operating head 505F to move the operating slides 505E forward (downward), vide Figures 10 and 13, so as to bring the clamping slides 505, moved by  
30 the co-operation between the oblique parts of the operating slots 505D and the operating studs 505C, close to the rear (upper) face of the anvil 503A, 503B, thus creating a situation analogous to that shown in Figure 4. At this point it should, however, be noted that the ob-

lique forward (downward) and inward movement of the clamping slides cause their forward end to exert a certain inwardly directed force on the tissues thus being clamped, thus counteracting any tendency for these tissues to slip off from the anvil.

Continued movement of the arm 505G towards the "stationary" arm 505H will, of course, create further forward (downward) movement of the operating slides 505E, vide Figures 11 and 14. The in-line parts of the operating slots 505D will now hold the clamping slides 505 in a clamping position, holding the tissues to be joined in the same manner as shown in Figure 4, while the final part of the movement will cause the oblique parts of the operating slots 505D to advance the stapling plungers 506 and cause the latter to insert the staples (not shown) and bend them in co-operation (in contact) with the staple-bending recesses 504 in the same manner as shown in Figure 5. All of these recesses are (of course) placed at an outwardly directed angle of same substantially 30°.

At this point, the anastomosis has been established, after which the instrument can be removed according to the principles illustrated by Figures 6-8, the surgeon previously having released the pressure on the arm 505G, allowing the spring 505I to act in the opposite direction, causing the parts 506, 505, 505E and 505F to return to the positions shown in Figure 9. If the core member 502CA, 502CB and the clamping slide housing 505A, 505B were unitary components, i.e. each made in one piece, this removal would have to be effected by pulling the instrument away from the anastomosis towards the free end of the bypass vessel (not shown). One prerequisite for so doing is, obviously, that such a free end exists, i.e.

that the bypass vessel is not part of an anastomosis at the other end.

5 In order to make it possible to remove the instrument from a bypass vessel without a free end, the components surrounding it, i.e. surrounding the passage 502D, are constituted by downstream parts 502CA, 505A and 503A and upstream parts 502CB, 505B and 503B, respectively of the core member, the clamping-slide housing and the anvil, 10 respectively. (The expressions "upstream" and "downstream" refer to the direction of flow in the coronary artery being operated upon when the instrument is placed in the preferred orientation relative to the artery, i.e. with the blood flowing towards the left in Figure 15).

15 The upstream part 505B of the housing 505A, 505B is releasably connected to the downstream part 505A by means of hook-and-pin connections, cf. Figures 9, 16 and 21, constituted by recesses 505AB in the downstream part 505A adapted to receive projections 505BB on the upstream 20 part, holding slots 505AC and 505BC being formed in alignment with the recesses 505AB and the projections 505BB, respectively, and adapted to receive removable holding pins 505K.

25 When the core member 502CA, 502CB and the clamping-slide housing 505A, 505B are assembled with the holding pins 505K in place as shown in Figures 9 and 16, the housing 505A, 505B will keep the core member 502CA, 502CB from coming apart. Conversely, when the holding pins 505K 30 have been pulled up, both the housing 505A, 505B and the core member 502CA, 502CB can easily be divided by simply pulling them apart, thus making it possible to remove the apparatus from the bypass vessel in a lateral direc-

tion. During this operation of dividing the core member and the housing, the various parts associated with them will, of course, have to be divided or liberated. The means for achieving this are not shown in detail, as any  
5 normally skilled mechanical technician or toolmaker should be able to devise the requisite mechanism without further guidance from the present description.

LIST OF PARTS

	1	anastomosis instrument
	2	anvil tube
5	3	anvil
	4	staple-bending recess
	5	clamping tube
	6	stapling plunger
	7	staple
10	8	staple-holding recess
	9	bypass vessel
	10	end region
	11	coronary artery
	12	edge region
15	13	fin or finger
	501	anastomosis instrument
	502A,B	anvil tube
	502CA,CB	core member
20	502D	central passage
	503A,B	anvil
	504	staple-bending recess
	505	clamping slide (and stapling-plunger guide)
	505A,B	clamping-slide housing
25	505AB	recess
	505AC	slot
	505BB	projection
	505BC	slot
	505C	clamping-slide operating stud
30	505D	operating slot
	505E	operating slide
	505F	common operating head
	505G	arm )
	505H	arm ) pair of tongs

505I	spring
505K	holding pin
506	stapling plunger
506C	stapling-plunger operating stud

CLAIMS

1. Method of connecting an end region (10) of a first vessel (9) to the side of a second vessel (11) by carrying out an end-to-side anastomosis, said method  
5 being of the kind comprising the following steps a-d:
- a) forming an opening in the side of said second vessel (11),
- b) inserting in said opening an anastomosis instrument (501) carrying said first vessel (9) in a  
10 longitudinal cavity (502D) and with said end region (10) everted about a circumferential member (503A, 503B) constituting a forward portion of said instrument (501) in such a manner, that the intima side of said end region  
15 (10) comes into contact with the intima side of said second vessel (11) at an edge region (12) of said opening,
- c) joining said end region (10) to said edge region (12) by inserting penetratingly therethrough and  
20 leaving therein a plurality of spiked members, and
- d) removing said instrument (501) from the joint formed between said first (9) and second (11) vessels,
- 25 said steps a-d being carried out by
- e) the use of an anastomosis instrument (501) comprising
- e1) an anvil assembly (502A, 502B, 503A, 503B) comprising a circumferential anvil member (503A, 503B) and in which said first vessel (9) may be  
30 placed with its end region (10) everted about said anvil member (503A, 503B) with the terminal part of said end region facing rearwardly,
- e2) rearwardly facing staple-bending recesses (504)

- e3) provided in said anvil member (503A, 503B),  
clamping members (505) adapted to be moved  
towards said anvil member (503A, 503B) so as to  
make it possible to clamp together therebetween  
said end region (10) on said first vessel (9)  
and an edge region (12) on said second vessel  
(11), and
- e4) stapling plungers (506) movable relative to  
said anvil member and adapted to insert staples  
penetratingly through said clamped end (10)  
and edge (12) regions into engagement with  
said stapling-bending recesses (504) so as to  
bend permanently said staples into a shape, in  
which they hold said end (10) and edge (12)  
regions together,

characterized by

- f) the use of an instrument (501), in which said  
stapling plungers (506) are slidable in direc-  
tions forming acute angles with the longitudinal  
axis of said longitudinal cavity (502D) and  
converging in a region forward of said circum-  
ferential anvil member (503A, 503B).

2. Method according to claim 1, characterized by  
the use of an instrument (501), in which said clamping  
members (505) are slidable in directions parallel to  
those, in which adjacent ones of said stapling plungers  
(506) are slidable.

3. Method according to claim 1 or 2, characterized  
by the use of an instrument (501), in which parts (502CA,  
502CB, 503A, 503B, 505A, 505B) surrounding said passage  
(502D) are releasably interconnected (505AB, 505BB, 505AC,  
505BC, 505K) so as to enable said passage (502D) to be

split lengthwise.

4.           Anastomotic instrument (501) for carrying out  
the method of any one or any of the claims 1-3 and of  
5   the kind comprising

- a)           an anvil assembly (502A, 502B, 503A, 503B)  
             comprising a circumferential anvil member (503A,  
             503B) and in which said first vessel (9) may be  
10           placed with its end region (10) everted about  
             said anvil member (503A, 503B) with the terminal  
             part of said end region facing rearwardly,  
b)           rearwardly facing staple-bending recesses (504)  
             provided in said anvil member (503A, 503B),  
c)           clamping members (505) adapted to be moved  
15           towards said anvil member (503A, 503B) so as to  
             make it possible to clamp together therebetween  
             said end region (10) on said first vessel (9)  
             and an edge region (12) on said second vessel  
             (11), and  
20    d)           stapling plungers (506) movable relative to  
             said anvil member and adapted to insert staples  
             penetratingly through said clamped end (10)  
             and edge (12) regions into engagement with  
25           said stapling-bending recesses (504) so as to  
             bend permanently said staples into a shape, in  
             which they hold said end (10) and edge (12)  
             regions together,

characterized in

- e)           that said stapling plungers (506) are slidable  
30           in directions forming acute angles with the  
             longitudinal axis of said longitudinal cavity  
             (502D) and converging in a region forward of  
             said circumferential anvil member (503A, 503B).

5. Instrument (501) according to claim 4, characterized in that said clamping members (505) are slidable in directions parallel to those, in which adjacent ones of said stapling plungers (506) are slidable.

5

6. Instrument (501) according to claim 4 or 5, characterized in that parts (502CA, 502CB, 503A, 503B, 505A, 505B) surrounding said passage (502D) are releasably interconnected (505AB, 505BB, 505AC, 505BC, 505K) so as to enable said passage (502D) to be split lengthwise.

10

7. Instrument (501) according to claim 5 or 6, characterized in

- 15 a) that said clamping members (505) are provided with first laterally extending operating studs (505C),
- b) that said stapling plungers (506) are provided with second laterally extending operating studs (506C), and
- 20 c) that said first (505C) and second (506C) operating studs are adapted to co-operate with common angular operating slots (505D) in likewise common operating slides (505E) adapted to be operated by a manually operable mechanism (505F, 505G, 505H, 505I) common to all operating slides (505E), all in such a manner, that
- 25 c1) in an initial phase of movement of said operating slides (505E) (Figures 9 and 12 to Figures 10 and 13), the clamping members (505) move into close adjacency to said anvil member (503A, 503B), and
- 30 c2) in a final phase of movement of said operating slides (505E) (Figures 10 and 13 to Figures 11 and 14), the stapling plungers (506) move into

a staple-bending position close to said anvil member (503A, 503B).

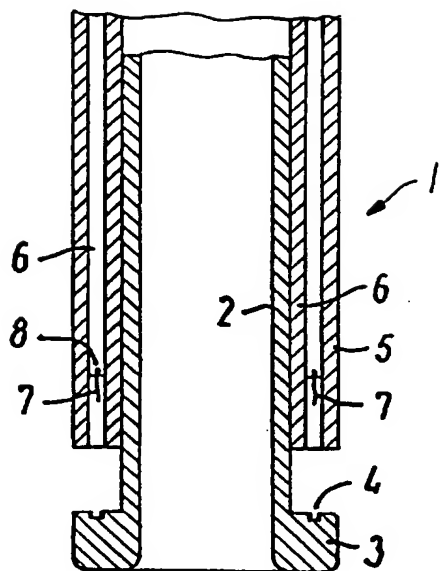


FIG. 1

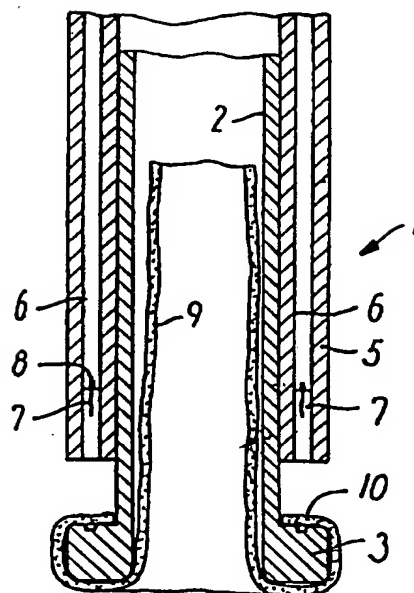


FIG. 2

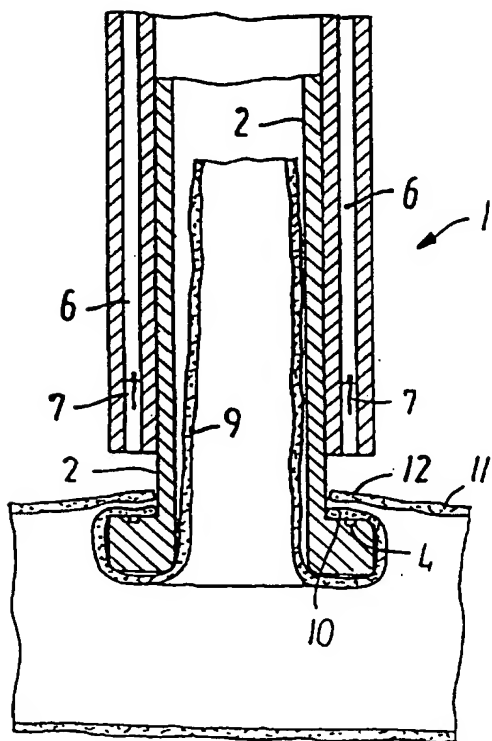


FIG. 3

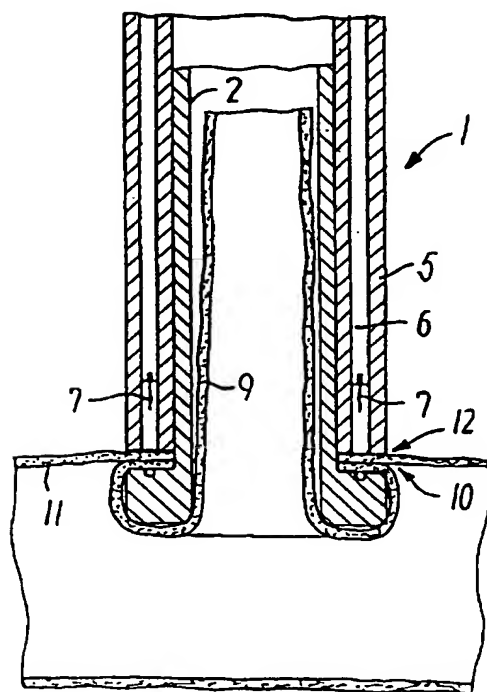


FIG. 4

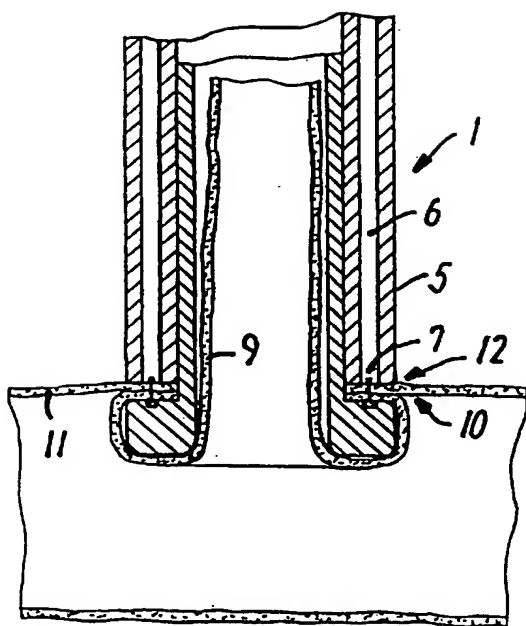


FIG. 5

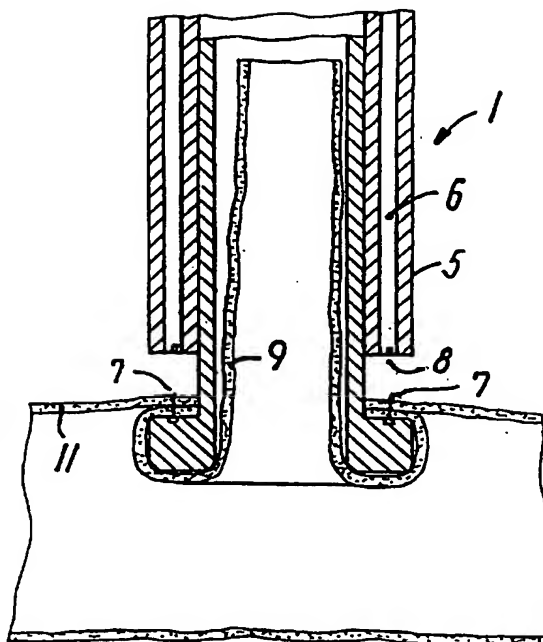


FIG. 6

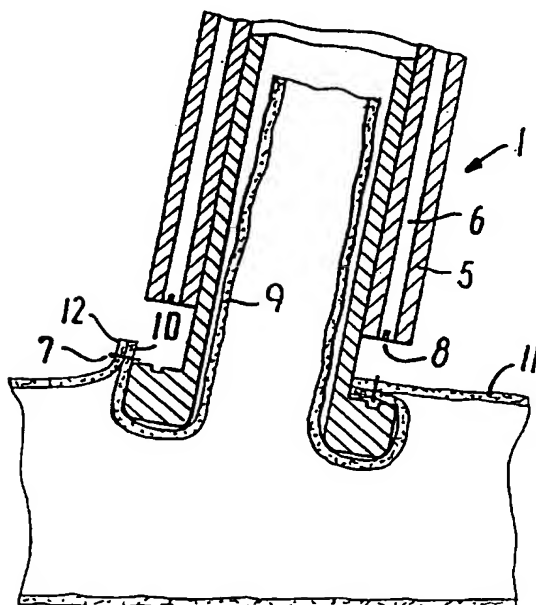


FIG. 7

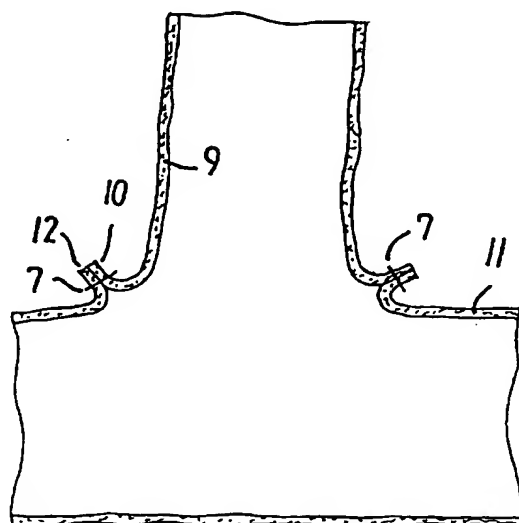


FIG. 8

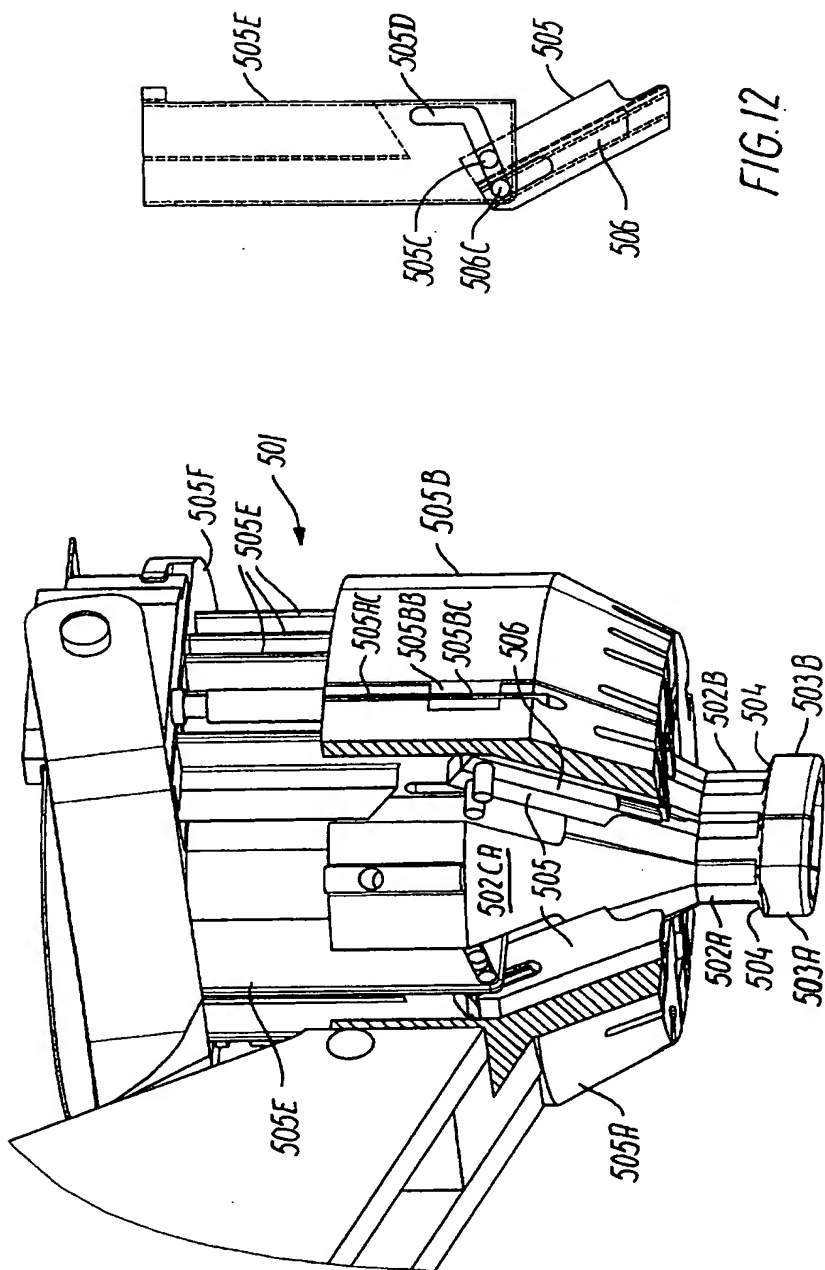


FIG. 9

FIG. 12

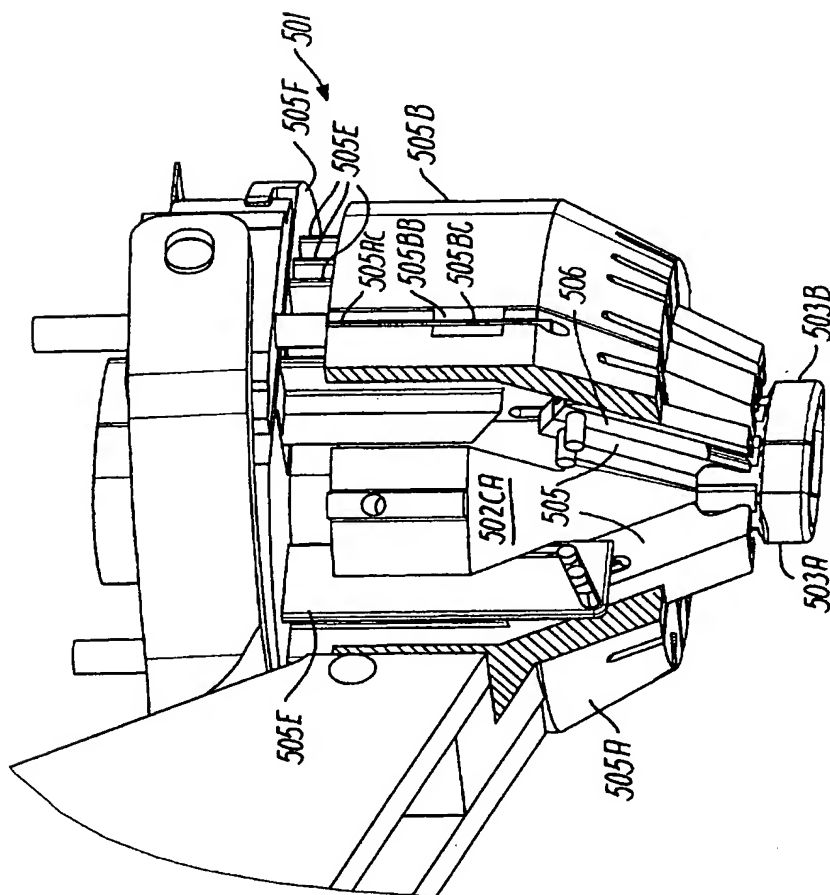


FIG. 10

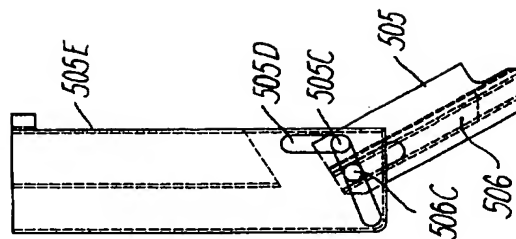


FIG. 13

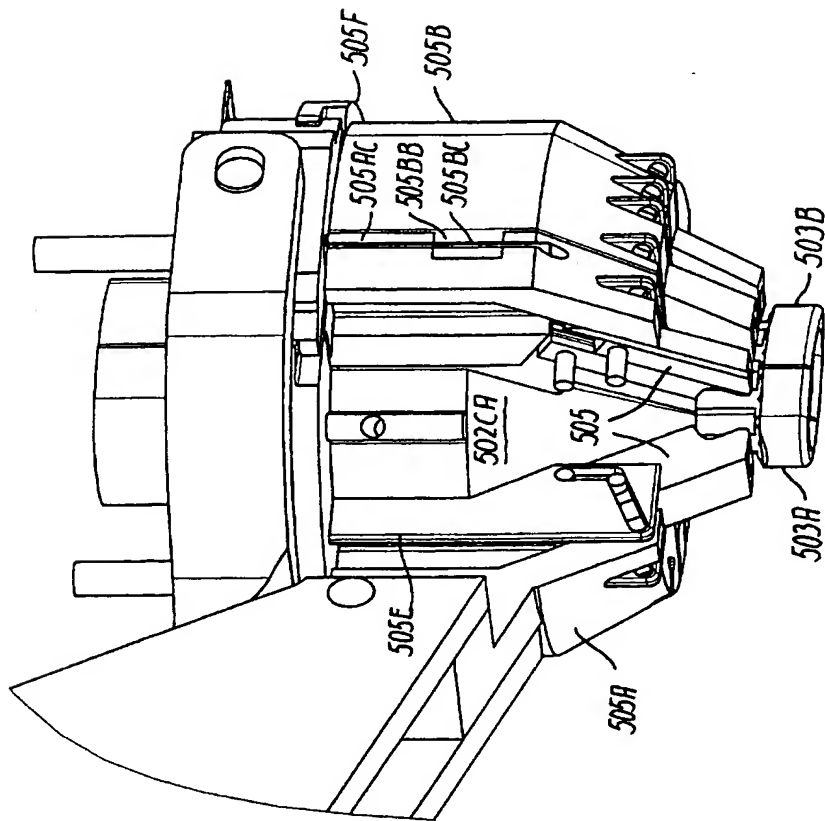


FIG. 11

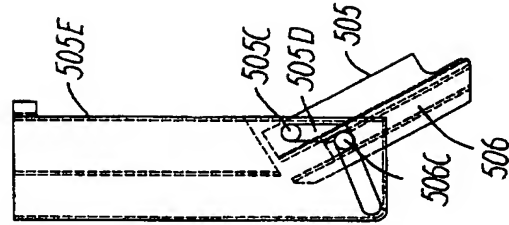
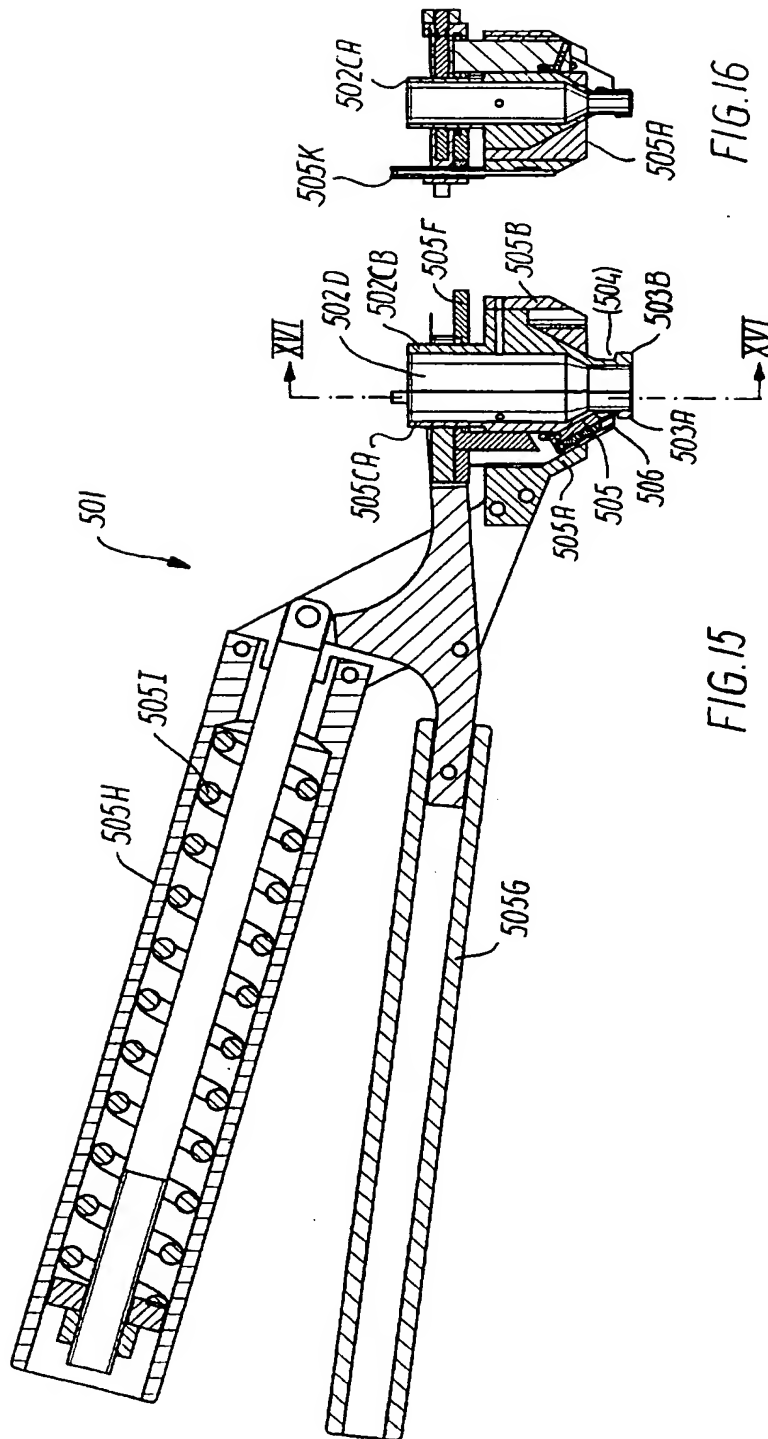


FIG. 14



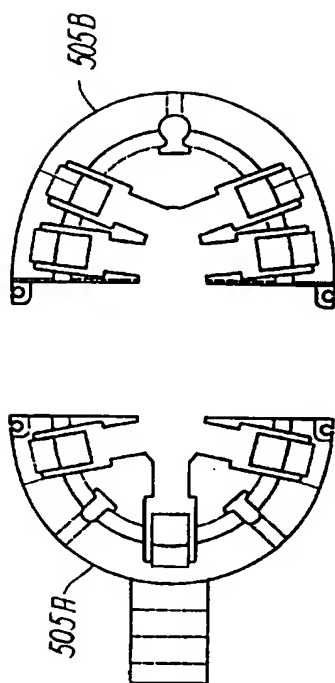


FIG. 20

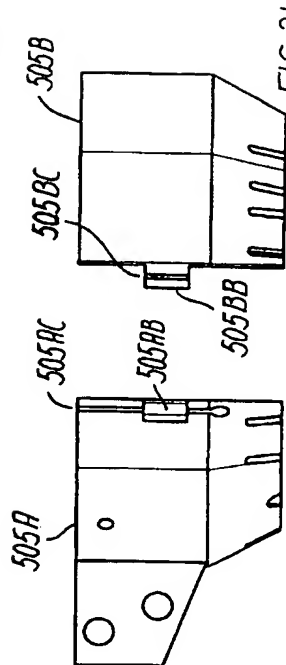


FIG. 21

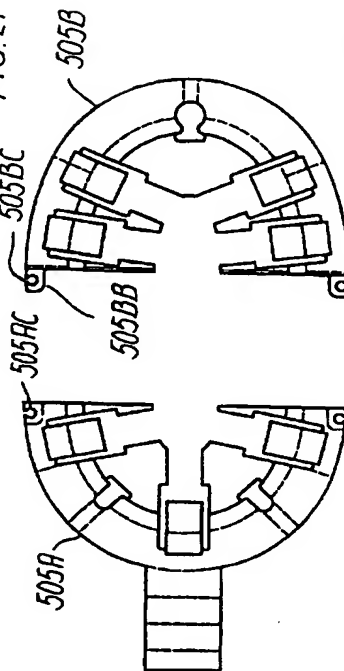


FIG. 22

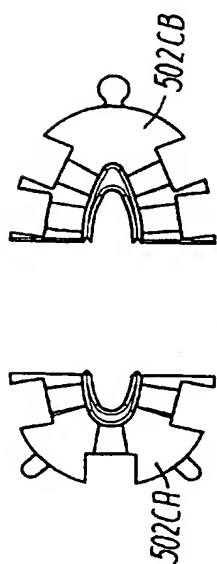


FIG. 17

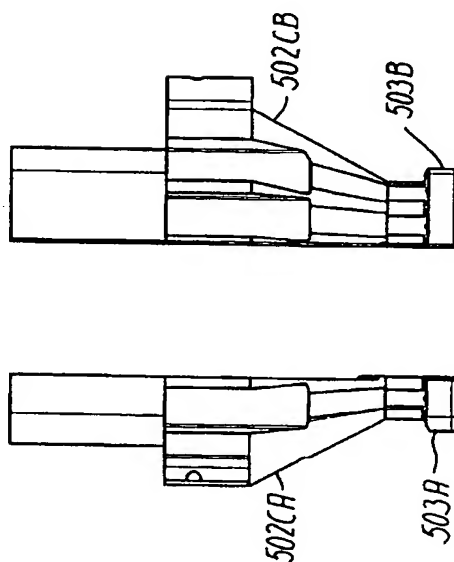


FIG. 18

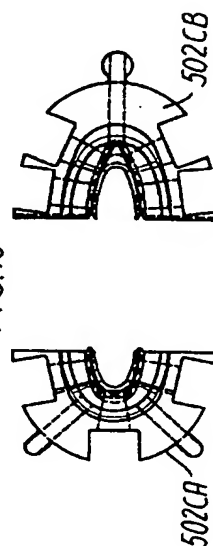


FIG. 19

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/DK 96/00197

<b>A. CLASSIFICATION OF SUBJECT MATTER</b>		
<b>IPC6: A61B 17/115</b> According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols)		
<b>IPC6: A61B</b>		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
<b>SE,DK,FI,NO classes as above</b>		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5292053 A (F.BILOTTI ET AL.), 8 March 1994 (08.03.94), figure 5 --	
A	US 5205459 A (R.J.BRINKERHOFF ET AL.), 27 April 1993 (27.04.93), figure 5 --	
A	US 5119983 A (D.T.GREEN ET AL), 9 June 1992 (09.06.92), figure 2 -- -----	
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search		Date of mailing of the international search report
17 February 1997		20 -02- 1997
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86		Authorized officer  Anette Hall Telephone No. +46 8 782 25 00

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 96/00197

## Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1-3  
because they relate to subject matter not required to be searched by this Authority, namely:

A method for treatment of the human body by surgery. This is subject matter which the International Searching Authority is not required to search under Article 17(2) (a) (i) and Rule 39 (iv).

2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

International application No.  
PCT/DK 96/00197

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 5292053	08/03/94	AU-B- 654371	03/11/94
		AU-A- 2109792	25/02/93
		CA-A- 2076602	24/02/93
		EG-A- 19853	31/05/96
		EP-A- 0536882	14/04/93
		GR-A- 92100358	07/06/93
		JP-A- 5212041	24/08/93
		US-A- 5205459	27/04/93
		US-A- 5271544	21/12/93
		US-A- 5275322	04/01/94
		US-A- 5285945	15/02/94
		US-A- 5333773	02/08/94
		US-A- 5350104	27/09/94
		US-A- 5533661	09/07/96
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		AU-A- 2109792	25/02/93
		CA-A- 2076602	24/02/93
		EG-A- 19853	31/05/96
		EP-A- 0536882	14/04/93
		GR-A- 92100358	07/06/93
		JP-A- 5212041	24/08/93
		US-A- 5271544	21/12/93
		US-A- 5275322	04/01/94
		US-A- 5285945	15/02/94
		US-A- 5292053	08/03/94
		US-A- 5333773	02/08/94
		US-A- 5350104	27/09/94
		US-A- 5533661	09/07/96
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		AT-T- 127328	15/09/95
		AU-B- 607495	07/03/91
		AU-A- 1659488	01/12/88
		AU-A- 6984191	28/03/91
		CA-A- 1322923	12/10/93
		CA-A- 1322925	12/10/93
		DE-D, T- 3854244	25/01/96
		DE-D, T- 3854435	14/03/96
		DE-U- 8714082	18/02/88
		EP-A, B- 0293123	30/11/88
		EP-A, B- 0449394	02/10/91
		ES-T- 2074996	01/10/95
		ES-T- 2077153	16/11/95
		JP-B- 2538987	02/10/96
		JP-A- 63300751	07/12/88
		US-A- 5158222	27/10/92
		US-A- 5285944	15/02/94
		US-A- 5392979	28/02/95



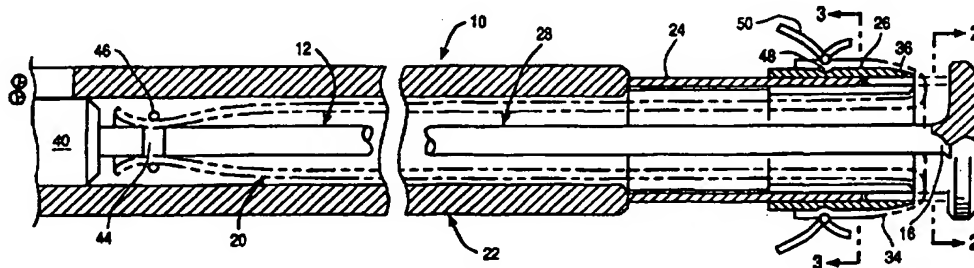
PCT

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International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: IMPROVED SURGICAL STAPLING INSTRUMENT AND METHOD THEREOF



(57) Abstract

A method and apparatus (10) for attaching a tubular graft (20) to a body structure (332) is disclosed. The apparatus (10) includes a central rod (12) with an anvil (14) attached at a distal end (16) thereof. Driver pins (24) move distally to eject staples (210) which are housed in a cartridge (26). The staple cartridge (26) has an outer circumference sufficient to accommodate everted end (34) of tubular graft (20), and an inner diameter sufficient to accommodate a majority of the tubular graft (2) therein. Accordingly, the method includes positioning the rod (12) in the graft (20), everting an end (34) of the graft around a shoulder (36) of the staple cartridge (26), inserting the anvil (14) through an opening (334) in the body structure (332), compressing the graft (20) and the body structure (332) between the anvil (14) and shoulder (36), and moving the driver pins (24) distally to engage and drive the staples (210), thus stapling the graft (20) to the body structure (332).

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## IMPROVED SURGICAL STAPLING INSTRUMENT AND METHOD THEREOF

### Field of the Invention

10 The invention relates generally to surgical stapling appliances and more particularly to an improved apparatus and method for the anastomotic surgical stapling of luminal organs, such as vascular lumens.

### BACKGROUND OF THE INVENTION

15 Various instruments are known in the prior art for end-to-end and end-to-side anastomotic surgical stapling together of parts of the alimentary canal (i.e., esophagus, stomach, colon, etc.). These instruments employ staple cartridges, generally in the shape of a hollow cylinder, of  
20 different sizes to accommodate tubular organs of varying diameters. End-to-end and end-to-side anastomoses are achieved by means of at least one ring of surgical staples.

The traditional technique for surgical stapling anastomosis is to position the stapling cartridge within the  
25 tubular organ to be stapled. The cut end of the tubular organ is inverted (i.e., folded inwardly) over the annular end of the staple cartridge creating an inverting anastomosis upon stapling. An essential requirement of the inverting anastomotic technique is the incorporation of knives within  
30 the staple cartridge housing to trim excess tissue from the anastomotic connection.

The prior art anastomotic stapling instruments form generally circular anastomotic connections, and have been largely limited to alimentary organs. With respect to end-to-  
35 side vascular anastomosis, circular connections, rather than an elliptical connections, are sometimes disadvantageous as they are less physiologic or natural. This unnatural connection may create turbulence in the blood flow as it

courses through the anastomosis, damaging the intima (i.e., inner wall) of the blood vessel and predisposing it to forming blood clots.

5 In the present state of the art, end-to-end and end-to-side anastomosis between blood vessels have typically been accomplished by hand-sewn suturing techniques. These techniques are time consuming, not as reliable as stapling, and subject to greater human error than stapling. Current stapling instruments used for alimentary canal are not  
10 suitable, however, for vascular anastomosis due to their large sizes and inability to provide non-circular and low turbulence anastomoses. A typical prior art instrument has a circumference of approximately 8 cm (3 in), far too thick to accommodate coronary arteries and veins, which have  
15 circumferences ranging from .50 to 1.0 cm and from 1.5 to 2.5 cm, respectively.

An additional drawback of prior stapling instruments is the inability to provide an everted (i.e., folded outwardly) anastomosis. An inverted vascular anastomosis  
20 would expose the cut ends of the blood vessels to the vessel lumen and could lead to the formation of blood clots. For this reason, hand-sewn everted anastomoses for vascular connections are preferable, despite time and reliability drawbacks.

25 Accordingly, it is a general object of the present invention to provide an improved instrument and method for vascular anastomosis.

It is also an object of the present invention to provide a surgical stapling instrument small enough to  
30 accommodate vascular lumens.

Another object of the present invention is to provide a surgical stapling instrument for everted anastomosis.

35 Another object of the present invention is to provide a method for surgical stapling that does not require the removal of excess tissue from the anastomotical connection.

Still another object of the present invention is to provide an instrument and method for vascular anastomosis that is less time-consuming and more reliable than the prior art.

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Still another object of the present invention is to provide an instrument and method for vascular anastomosis that is less time-consuming and more reliable than the prior art.

#### SUMMARY OF THE INVENTION

The present invention provides a novel instrument and method for vascular anastomoses which overcomes the drawbacks of prior art designs and achieves the aforesaid advantages.

Very generally, the surgical stapling instrument of the present invention is for stapling a tubular tissue structure having at least one distal end to a luminal

structure, such as a vascular lumen or another tubular tissue structure. The instrument comprises a rod having a circumference sufficient to pass within the tubular tissue structure, an anvil mounted on the rod, and a generally  
5 tubular staple cartridge for containing a plurality of staples. The anvil has an array of staple deforming means thereon and is of a size sufficient to pass through a surgically formed opening in and to be accommodated within the luminal structure. The inner passage of the staple cartridge  
10 is sufficient to axially accommodate the tubular tissue structure between the rod and the inner surface of the staple cartridge, and sufficient to allow the staple cartridge to be moved axially along the rod. The staple delivery end of the staple cartridge is positioned toward the staple deforming  
15 means of the anvil and has an outer dimension small enough so that the tubular tissue structure can be everted thereover. A clamping mechanism secures the everted portion of the tubular tissue structure and the luminal structure adjacent to the surgically formed opening between the staple cartridge and the  
20 anvil. A plurality of staples may then be ejected to pass through the everted portion of the tubular tissue structure and the luminal structure to engage the staple deforming means to deform the staples and create a bond between the tubular tissue structure and the luminal structure.

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#### DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIGS. 1 - 7, there is shown a structural embodiment of the present invention which is best suited for anastomotic stapling of a tubular vessel having two  
30 distal or untethered ends. As will be evidenced by the detailed description below, this embodiment, i.e., distal stapler, is ideal for use during cardiopulmonary bypass surgery for making the primary anastomotic connection of a bypass vein to a coronary artery or to the aorta.

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Referring now to FIG. 1, a portion 10 of the wholly configured distal stapler of the present invention, as shown in FIG. 7, comprises an elongated central rod 12 with anvil 14 mounted at its distal end 16. Anvil 14 is in the form of a

circular, elliptical or tear drop-shaped disk and is mounted, by suitable means such as welding, to the end of central rod 12 transversely thereof and at the center of the anvil. The edges of anvil 14 are beveled or otherwise generally rounded to enable anvil 14 to slip easily through incisions in vascular walls - much like a button through a button hole.

The central rod 12 has a circumference sufficient to permit the rod to axially extend through a tubular vessel, indicated in phantom at 20, to be stapled. Central rod 12 also axially extends within tubular housing 22, driver pins 24 and staple cartridge 26, together forming a contiguous shaft 28 having an inner circumference sufficient to accommodate tubular vessel 20 sandwiched between them and central rod 12. Staple cartridge 26 has an outer circumference sufficient to accommodate everted end 34 of tubular vessel 20. Lip 36 of cartridge 26 is tapered to facilitate eversion of tubular vessel 20. Anvil 14 has circumference of a size equivalent to the outer circumference of staple cartridge 16.

Circumferences of vascular vessels range from .50 to 1.0 cm for coronary arteries and from 1.5 to 2.5 cm for veins. Accordingly, all circumferences, discussed above, of stapler 10 are of a size to optimally coaxially accommodate the vein to be stapled.

The end of central rod 12 opposite anvil 14 is centrally mounted, preferably welded, on a cylindrical base 40 which extends coaxially within tubular housing 22 (as shown in FIG. 7 by reference number 106) and has a circumference sufficient to be slidable within tubular housing 22. The accommodated tubular vessel 20 extends along central rod 12 to cylindrical base 40. Provided on the surface of central rod 12 proximal to base 40 is circumferential groove 44 for facilitating the securing of tubular vessel 20 to rod 12 by means of string 46. Similarly, circumferential groove 48 and string 50 are provided to secure everted end 34 of vessel 20 to staple cartridge 26. An alternative embodiment of staple cartridge 26 for securing an everted vein comprises tiny hooks around the circumference at end 36 of the cartridge. Other

suitable means for accomplishing the securing function may be used as well.

Referring now to FIG. 2, there is shown a cross-sectional view of stapler 10 of the present invention in the direction of arrows 2-2 of FIG. 1. Here, the staple delivery end 60 of a circular staple cartridge is illustrated encasing a circular array of staple delivery means or staple shafts 62. The present invention is not limited to a single staple shaft array, however. It is commonly known in the art to employ a plurality of concentric arrays or rows of staple shafts for anastomotic procedures. Extending from staple shaft array 62, is an array of narrow channels 68, each narrow channel corresponding to each staple shaft. Channel array 68 is used solely for manufacturing purposes and is not a necessary element of the invention. Central rod 64 and its base 66 are axially and centrally located within the cylindrical staple cartridge 60.

FIG. 3 shows the underside view of anvil 70 in the direction of arrows 3-3 of FIG. 1. The anvil 70 has an array 74 of means for deforming staples. Central rod attachment 72 is centrally located on anvil 70 which provides an array of staple deforming means 74, comprised here of an array of recess pairs, for bending staples projected from corresponding array of staple shafts 62 of the staple cartridge of FIG. 2.

Depicted in FIG. 4 is a cross-sectional view of anvil 70 in the direction of arrows 4-4 of FIG. 3. Each recess pair 76 is curved to bend staple legs radially inward. The projected staples can be made to bend radially inward or radially outward depending on the spacing 78 between the recess of each paired recess 76. Alternatively, each recess can be positioned orthogonal to its present position to bend the staple legs at right angles to their axis of projection.

Although the present invention is primarily described and depicted as forming staple bonds that are circular and as having component circumferences that are circular, other embodiments are realized for forming staple bonds having elliptical, tear drop or other generally oval circumferences. Accordingly, the anvil and associated staple

recess array, and the cartridge housing and associated staple shaft array of these alternative stapler embodiments have circumferences in the shape of the desired staple bond. For example, FIGS. 5 and 6 illustrate an anvil and staple cartridge, respectively, having tear-drop shaped circumferences.

FIG. 5 shows a cross-sectional view of a tear-drop shaped staple cartridge. The staple delivery end 80 of the staple cartridge is illustrated encasing a tear drop array of staple delivery means or staple shafts 82. Extending from staple shaft array 82, is an array of narrow channels 84, each narrow channel corresponding to each staple shaft. Channel array 84 is used solely for manufacturing purposes and is not a necessary element of the invention. Central rod 86 and its base 88 are coaxially and centrally located within the cylindrical portion of tear drop staple cartridge 80.

FIG. 6 shows the underside view of a tear drop shaped anvil 90. Central rod attachment 92 is centrally located on the circular portion of anvil 90 which provides an array of staple deforming means comprised of recess pairs 94 for bending staples projected from corresponding array of staple shafts 82 of the staple cartridge of FIG. 5.

Referring now to FIG. 7, there is shown stapler 100 of the same embodiment depicted in FIGS. 1 - 4. A tubular housing 102 coaxially contains central rod 104 and rod base 106, the end of central rod 104 opposite that of anvil 114 being suitably mounted, such as by welding, to rod base 106 (connection not shown). Threadedly mounted to and extending perpendicular from rod base 106 is a short stem 108, positioned at approximately half the length of base 106. The top of stem 108 has cylindrical knob 110 transversely mounted. Stem 108 is moveable within narrow channel 112, cut within housing 102 and running parallel to the axis traveled by central rod 104 and rod base 106. Channel 112 limits the rotational movement of stem 108 and thereby maintains a proper radial orientation between anvil 114 and staple cartridge 116 during reciprocation.

Weldedly mounted to and protruding perpendicularly from cylindrical face 118 of housing 102 and paralleling rod 104 is cylindrical array of staple driver pins 120, all drivers pins being identical and each having the form of a solid parallelogram. Staple cartridge 116 encases, from end to end, cylindrical array of hollow staple shafts 122 which holds a plurality of preloaded staples (not pictured). All shafts 122 are identical and each has height and width dimensions such that a corresponding staple driver pin 120 is slidable therein.

In order to have an optimally functioning stapler, it is necessary to maintain a clean and clear passageway for central rod 104, base 106 and staple shafts 122. Accordingly, one embodiment of the present invention comprises a disposable cartridge which is disposed of and replaced after one anastomotic stapling. Another embodiment provides a slidable sleeve around the driver pin array to prevent blood and tissue from getting caught therein.

For anastomosis to be successful, it is imperative not to injure the living tissue being stapled by overcompressing it between anvil 114 and staple cartridge 116 or by a staple bond that is exceedingly tight. Accordingly, overcompression of the tissue is pher embodiments are known in the prior art for accomplishing this objective. For example, U.S. Patent No. 4,575,468 employs mutually coacting stops located on the inner surface of a tubular housing and on the surface of a coaxial rod to provide variable degrees of engagement between tissues to be stapled so as to ensure against overcompression of the tissue. A spring-loaded engagement between the rod and tubular housing is also applicable for the present invention. Other means suitable for this purpose will be apparent to those having ordinary skill in the art.

Finally, FIG. 7 illustrates threaded end 124 of rod base 106 which extends beyond the length of housing 102 to threadedly engage with cylindrical nut 126 which has internally threaded throughbore 120 extending the full length of cylindrical nut 126 to allow end 124 to exit therethrough.

FIGS. 8 and 9 illustrate the mechanical interaction between the staple driver, staple cartridge and anvil upon engagement. FIG. 8 illustrates staple driver array 200 mounted on face 202 of tubular housing 204 slidably engaged within staple shaft array 206 of staple cartridge 208. Staple array 210 is projected from staple cartridge 208 and through the tissues to be stapled (not shown). FIG. 9 shows a close-up of a staple being driven by driver pin 252 and projecting through cartridge 254 through tissues 256 and 258. The legs 260 and 262 of staple 250 then engage with and bend along the curved recesses 264 and 266, respectively, of anvil 268 to form a bond between tissues 256 and 258.

Referring now to FIGS. 10 - 16, with like numbers referring to like elements, there is illustrated the steps of the anastomotic procedure using the structural embodiment described above. Now referring to FIG. 10 specifically, the anvil-headed end of rod base 302 is inserted into transected vein 304 having a length in the range of 10 - 18 cm (4 - 7 inches). End 308 (the end to be stapled) of vein 304 is positioned proximate to anvil 306. Opposing end 310 of vein 304 is tied with string 312 to central rod 314 at a circumferential depression (not shown) proximate to base 302.

FIG. 11 shows the step of inserting central rod 314 with attached vein 304 into staple cartridge 318 and tubular housing 316 such that staple cartridge 318 is proximate to anvil 306. FIG. 12 illustrates the next several steps of the method of the present invention which can be performed in any order. The end of vein 304 is everted over staple cartridge 318 and tied with string 320 securing it to staple cartridge 318 (covered by vein 304). Threaded stem 322 of cylindrical knob 324 is threadedly engaged with a threaded bore (not shown) base 302, the bore being aligned with narrow channel 326. Cylindrical nut 328 is threadedly engaged with the threaded end 300. As indicated in FIG. 13, anvil 306 is positioned within lumen 330 of vascular artery 332 via incision 334. A cross-section of a portion of vein 304 is shown everted over the staple delivery end of staple cartridge 318.

In FIG. 14, central rod 314 (not visible) and rod base 302 (not visible) are optimally coaxially positioned within tubular housing 316 by means of sliding knob 324 along channel 326 toward vascular artery 332. Nut 328 is rotated in a clockwise direction to engage it with tubular housing 316 causing rod base 302 to become rigidly interconnected with nut 328. As the clockwise turning continues, rod base 302 is drawn through the bore in nut 328, bringing the staple cartridge 336 and anvil 306 within artery 332 together. An embodiment employing mutually coacting stops (not shown) would, at this point, be at the first coacting position or the "loaded" position. The clockwise motion is continued so that everted vein 304 engages with the wall of artery 332 and until the staple drivers (not visible) are actuated, driving the staples (not visible) through the tissues to create a bond 338 (FIG. 15). If mutually coacting stops are employed, the configuration would be in the "firing" position.

Finally, FIG. 16 illustrates heart 350 having aorta 352, pulmonary artery 354, right atrium 356, right ventricle 358, left ventricle 360, left atrial appendage 362, right coronary artery 364, left anterior descending artery 368, and diagonal artery 370. Here, vein 304 has been anastomotically stapled to left anterior descending artery 368.

To complete the anastomotic procedure of the bypass vein 304, the unstapled end of the anastomotized vein 304 must now be connected to aorta 352. However, another structural embodiment of the present invention, referred to as the "proximal" stapler, is needed since the embodiment described above, i.e., the "distal" stapler, requires the vein to have two distal or untethered ends. Accordingly, FIGS. 17 - 28 describe a structure and method thereof for a second embodiment of the present invention which is suited for the anastomotic stapling of a tubular vessel having only one distal end, the other end having already been anastomotically stapled.

Referring now to FIGS. 17 - 19, with like numbers referencing like elements, there is shown anastomotic stapler 400 having handle 402 with elongated vessel rod 404 and

elongated driver rod 406 mounted perpendicularly to handle face 408 and parallel to each other, both being of approximately the same length. Vessel rod 404 has a centrally mounted generally circular anvil 410. Vessel rod 404 has a circumference sufficient to coaxially accommodate a tubular vessel (not shown) to be stapled to the aorta. Driver rod 406, having threaded end 412 and handle 414, extends through bore 416 of handle 402.

Stapler 400 also comprises staple cartridge 418, enlarged in FIG. 18 for purposes of describing its detail. Referring then to FIG. 18, there is shown the staple cartridge of FIG. 17 in its open position having top and bottom units 420 and 422, respectively. Units 420 and 422 are engaged at one side by hinge 424 which allows cartridge 418 to be opened and closed. Staple cartridge 418 has two parallel bores 426 and 428 with inner circumferences sufficient to coaxially accommodate vessel rod 404 with a coaxially accommodated vein (not shown) and driver rod 406, respectively. Staple delivery end 430 extends from staple cartridge 418 along the axis of bore 426 to accommodate the everted end of a vein to be stapled. Bore 428 is internally threaded to be threadably engagable with driver rod end 412.

For a proper fit between units 420 and 422, a detent-recess pair is provided having detent 432 extending from inner surface 434 of top unit 420 which mates with recess 436 within inner surface 438 of bottom unit 422. To secure closing, a curved clip 440 is provided to fit around cylindrical casing 442 of bore 428.

When in a closed position, staple cartridge 418 has cylindrical staple delivery means or staple shaft array (not shown) encased in staple delivery end 430 which mates with cylindrical driver pin array 444 mounted on driver 446. Both the hollow shafts and the solid driver pins have height and width measurements that allow them to be slidably engagable with each other. Driver 446 is slidable along surface 448 of top unit 420 and surface 450 of bottom unit 422 to the point of engagement with shoulder 452 of top unit 420 upon which driver pin array 444 becomes engaged within the staple shaft

array, projecting preloaded staples from the end of staple delivery end 430. Shoulder 452 limits the engagement of driver pin array 444 so that the tissue being stapled is not overcompressed. Modifications of the this embodiment can  
5 employ mutually coacting stops or spring-loaded type configurations between the driver and staple cartridge to prevent against overcompression of the tissue.

FIG. 19 shows a front view of staple cartridge 418 in its closed position with top unit 420 engaged with bottom  
10 unit 422. Clip 440 securely fits around cylindrical casing 442. Staple deforming end or staple shaft array 454 is shown on the face of staple delivery end 430.

FIGS. 20 - 28, with like numbers referencing like elements, depict the various steps of the anastomotic  
15 procedure using the structural embodiment in FIGS. 17 - 19 described above. Referring now to FIG. 20, vessel rod 500 is inserted through aorta 502 of heart 504 via incisions 506 and 508 on opposing walls of aorta 502 such that anvil 510 is centrally positioned within aorta 502.

In FIG. 21, the end of vessel rod 500 is then  
20 inserted into the distal end of vein 512 with anvil 510 still centrally positioned within aorta 502. Next, as shown in FIG. 22, vessel rod 500 with accommodated vein 512 is positioned within the corresponding bore 514 in open staple cartridge  
25 516. Rod 500 and vein 512 should be positioned such that a sufficient length of distal end 518 of vein 512 extends beyond the end of cartridge 516 such that distal end 518 can be everted over cylindrical sleeve 520 of cartridge 516 (See FIG. 23). Once vein 512 has been optimally positioned, staple  
30 cartridge 516 is clamped around it and secured with clip 522, illustrated in FIG. 24. Now, distal end 518 of vein 512 is everted over sleeve 520 and is securely tied with string 524.

Referring now to FIG. 25, driver rod 526 is slid  
into bore 528 of handle 530 and then threadedly engaged with  
35 bore 532 of staple cartridge 516. FIG. 26 shows a close-up of staple cartridge 516 as it appears in its closed position.

Moving now to FIG. 27, there is shown driver handle 534 rotated in a clockwise direction, bringing together anvil

510 and cylindrical sleeve 520. The clockwise rotation is continued until the aorta wall 502 is engaged with the distal end 518 of vein 512 upon which the staple driver pins (not visible) are fully engaged within each of the corresponding staple shafts (not visible), driving the staples (not visible) through the engaged tissue to create anastomotic bond 536 between aorta 502 and vein 512 (See FIG. 28).

Referring to Fig. 29, another stapler 600 is shown. The stapler 600 advantageously provides an actuator 602 for compressing the tissue layers to be stapled and a trigger 604 for firing the staples (not shown). By providing both the actuator 602 and trigger 604, the amount of tissue compression can be controlled independent of staple firing.

The stapler 600 includes a handle 606 with the actuator 602 being rotatably coupled to the proximal end of the handle 606. The actuator 602 has a groove 608 which engages a set screw 610 in the handle 606 so that the actuator 602 can only rotate relative to the handle 606. A rod 612 is threadably coupled to the handle 606 so that rotation of the actuator 602 moves the rod proximally and distally. The rod 612 extends through a housing 614 and an anvil 616 is connected to the distal end of the rod 612. As will be discussed in further detail below, the actuator 602 is rotated to move the anvil 616 relative to a shoulder 618 of the housing 614 for compressing the tissue layers to be stapled.

The trigger 604 is pivotally coupled to the handle 606 and actuation of the trigger 604 fires the staples (not shown) as will be described in further detail below. The trigger 604 engages a driver 620 which is biased toward the position of Fig. 29 by a spring 622. A stop 624 limits rotation of the trigger 604 beyond the position in Fig. 29. The driver 620 contacts and drives a shaft 626 which extends toward the distal end. The driver 620 preferably has a throughhole 628 having a square cross-sectional shape (not shown) through which the rod 612 extends. The rod 612 has a complementary square cross-sectional shape at a portion extending through the throughhole 628 to prevent rotation of the rod 612. The housing 614 also includes a tube 630 and a

guide 634 which has the shoulder 618. The tube is connected to the handle 606 by another set screw 632.

Referring to Fig. 30, the distal end of the stapler 600 is shown. The distal end of the shaft 626 engages a staple pusher 636. The staples (not shown) are positioned in cavities 638 and are driven toward recesses 640 in the anvil 616. The staple pusher 636 is slidably coupled to the guide 634 which guides the staple pusher 636 and defines the cavities 638 in which the staples are positioned. The guide 634 is preferably coupled to the tube 630 by a compression fit but may be connected to the tube 630 in any other manner. When the anvil 616 is moved toward the proximal end by rotation of the actuator 602, the tissue layers are compressed between the anvil 616 and the shoulder 618 of the guide 634 as will be described below in connection with Fig. 36.

Referring to Fig. 31, a cross-sectional view of Fig. 30 is shown along line I-I. The guide 634 preferably includes at least five, and more preferably at least six, cavities 638, however, any number of cavities 638 may be provided. The staple pusher 636 includes staple drivers 642 which are positioned in the cavities 638 and extend radially outwardly from a central tube 644. Referring to Fig. 32, another cross-sectional view of Fig. 30 is shown along line II-II. The recesses 640 of the anvil 616 are positioned and shaped to engage and deform the staples being driven from the cavities 638 and have a cross-sectional shape as shown in Fig. 4. The cavities 638 and recesses 640 may have any other configuration, including the tear drop shape of Figs. 5 and 6, without departing from the scope of the invention.

Referring to Figs 33-34, a preferred staple 646 is shown. The staple 646 includes a tissue compressing portion 648 extending between legs 449 for compressing the tissue layers being stapled. The tissue compressing portion 648 has a height A of preferably 0.040 inches while the overall height B of the staple is preferably 0.125 inches. The height A of the tissue compressing portion is preferably at least 15 %, and more preferably at least 25 %, and most preferably at least 30% of the overall height B of the staple 646. The

tissue compressing portion 648 is preferably solid between a top 650 and bottom 652 of the staple 646 so that the staple 646 is more rigid, however, the tissue compressing portion 648 may also be hollow between the top 650 and bottom 652. The bottom 652 of the tissue compressing portion 648 may also include tissue engaging features, such as atraumatic ridges, for securely grasping the tissue. The tissue compressing portion 648 permits controlled compression of the tissue while the top 650 of the staple 646 is still engaged by the staple pusher 636 for stability.

The staple 646 preferably includes a notch 654 which ensures that the legs 649 bend at the desired location. The legs 649 preferably have a width C of 0.010 inches. The sharp distal end of each leg is beveled at about 45E and the notch 654 is preferably a distance D of 0.025 inches from the sharp distal end. The notch 654 preferably has a radius of curvature of about 0.005 inches. Referring to Fig. 34, the staple 646 preferably has a thickness E of 0.010 inches and a width F of 0.072 inches. Although the dimensions given above are preferred, the staple 646 may have any other dimensions without departing from the scope of the invention.

Operation of the stapler 600 is now described in connection with attaching a graft 660 to a blood vessel such as an aorta or a coronary artery. Referring to Fig. 35, the rod 612 is detached from the stapler 600 by rotating the actuator 602 until the rod 612 is decoupled from the actuator 602. The graft 660, which can be either synthetic or natural, is then fitted over the rod 612 with a suture 656 securing the proximal end of the graft 660 to the rod 612. The rod 612 is then reattached to the actuator 602 so that the graft 660 is positioned almost entirely within the stapler 600.

Referring to Fig. 36, the distal end of the graft 660 is everted around the shoulder 618. The anvil 616 is then pushed through the opening in the body structure 662, which may be an aorta or a coronary artery, to which the graft 660 is being attached. The actuator 602 is then rotated to compress the body structure 662 and graft 660 between the anvil 616 and shoulder 618 as shown in Fig. 37. An advantage

of the stapler 600 is that the compressive force on the graft 660 and body structure 662 may be controlled independent of staple firing. Although it is preferred to movably couple the anvil 616 to the handle 606, the anvil 616 may be fixed to the handle 606 and the shoulder 618 may be movably coupled to the handle 606 for compressing the tissue layers.

Referring still to Fig. 37, the trigger 604 is manipulated to drive the staple pusher 636 and fire the staples 646. The staples 646 are forced against the recesses 640 of the anvil 616 and buckle at the notches 654 (Fig. 3ed, the actuator 602 is rotated to release compression of the tissue between the anvil 616 and shoulder 618. The anvil 616 and rod 612 are then removed from the graft 660 and the other end of the graft 660 is attached to another body structure, such as an aorta or a coronary artery, thereby completing the graft procedure.

Referring to Fig. 38, yet another stapler 700 is shown. The stapler 700 includes similar features to the stapler 600 of Figs. 29-37 and like reference numerals refer to like structure. The stapler 700 includes a handle 706 having an actuator 702 at the proximal end. The actuator 702 has a groove 708 which engages a set screw 710 for rotatably coupling the actuator 702 to the handle 706. A rod 712 is threadably coupled to the handle 706 so that rotation of the actuator 702 moves the rod 712 proximally and distally. An anvil 716 is connected to the distal end of the rod 712. Rotation of the actuator 702 moves the anvil 716 towards and away from a shoulder 718 of a housing 714 to control compression of tissue layers positioned therebetween as discussed above in connection with the stapler 600.

A trigger 704 is pivotally coupled to the handle 706 and actuation of the trigger 704 fires the staples (not shown). The trigger 704 engages a driver 720 which is biased toward the open position of Fig. 40 by a spring 722. A stop 724 limits rotation of the trigger 704 beyond the position in Fig. 40. The driver 720 contacts and drives a shaft 726 which extends toward the distal end. A tube 630 is also connected to the handle 706 by another set screw 732.

The anvil 716 is expandable from the collapsed position of Fig. 39 to the expanded position of Fig. 40. The anvil 716 is easier to withdraw through the graft after stapling is completed since the anvil 716 can assume the collapsed shape of Fig. 40. The expandable anvil 716 is moved from the collapsed shape to the expanded shape by an expander 717 which extends through the rod 712. The expander 717 is coupled to a knob 719 at the proximal end. The knob 719 is rotatably coupled to the actuator 702 so that rotation of the knob 719 moves the expander 717 distally and proximally. The distal end of the expander 717 has a conical member 721 which engages the anvil 716 to expand the anvil 716 as will be described in greater detail below. The expander 717 preferably has a square cross-sectional shape (not shown) at a portion 721 passing through the distal end of the rod 712 with the distal end of the rod 612 having a complementary shaped square throughhole 723. The square cross-sectional shape of the expander 711 and throughhole 723 prevent rotation of the expander 717 so that rotation of the knob 719 translates into longitudinal motion of the expander 717.

A distal portion 725 of the rod 712 has a reduced diameter so that the rod 712 is more flexible thereby permitting movement from the collapsed position to the expanded position. Referring to Fig. 39, the distal end of the stapler 700 is shown. The distal end of the shaft 726 engages a staple pusher 736. The staples (not shown) are positioned in cavities 738 and are driven toward recesses 740 in the anvil 716. The staple pusher 736 and guide 734 are the same as described above in connection with Figs. 30-32.

Referring to Fig. 41, a cross-sectional view of Fig. 38 along line III-III is shown. The expander 717 and anvil 716 are shown with the anvil 716 in the collapsed position. The anvil 716 preferably has at least four, more preferably at least five, and most preferably at least six anvil segments 716A. The rod 712 is split longitudinally along the distal portion 725 (Fig. 38) into six corresponding rod sections 712A (Fig. 40) which each carry one of the anvil segments 716A. Fig. 40 shows two of the rod segments 712A.

The rod segments 712A act as springs which permit deflection of the distal portion of the rod 712. The rod segments 712A bias the anvil segments toward the collapsed position of Fig. 39. Referring again to Fig. 41, the expander 717 includes  
5 ribs 731 which engage slots 733 in the anvil segments 716A to ensure proper spacing between the anvil segments 716A and prevent displacement of the anvil segments 716A when the staples are fired.

Referring to Fig. 42, a cross-sectional view of  
10 Fig. 39 along line IV-IV is shown. The expander 717 is moved toward the proximal end so that the larger diameter portion of the conical member 721 engages the anvil segments 716A and biases the rod segments 712A outwardly as shown in Fig. 39. Each of the anvil segments 716A include one of the recesses  
15 740 shown in Fig. 32 and the recesses 740 are positioned and shaped to engage and deform the staples being driven from the cavities 738 when the anvil 716 is in the expanded position. The anvil segments 716A preferably have a plan area in the collapsed shape which is smaller than the plan area of the  
20 recesses when the anvil segments 716A are in the expanded position so that the anvil segments 716A may be easily withdrawn from the stapled area after stapling is completed. The cavities 738 and recesses 740 may be in any other configuration, such as the tear drop shape of Figs. 5 and 6,  
25 without departing from the scope of the invention. The stapler 700 preferably uses the staple 646 described above in connection with Figs 34-36, however, any other staple may be used.

Operation of the stapler 700 is now described. The  
30 stapler 700 operates in essentially the same as the stapler 600 except for use of the expander 717. The rod 712 is decoupled from the actuator 702 and the expander 717 is decoupled from the knob 719. The rod 712 is then passed through the graft 760 with the anvil 716 in the collapsed  
35 shape. The rod 712 and expander 717 are then reattached to the actuator 702 and knob 719. The distal end of the graft 760 is everted around the distal end of the guide 734 and the anvil 716 is pushed through the opening in the body structure

to which the graft 760 is being attached. The knob 719 is then rotated so that the expander 717 moves distally and expands the anvil 716 to the expanded position of Fig. 40. Alternatively, the anvil 716 may be positioned in the expanded position before inserting the anvil 716 into the body structure. The actuator 702 is then rotated to compress the body structure and graft between the anvil 716 and shoulder 718. The trigger 704 is then actuated to drive the staple pusher 736 and fire the staples against the anvil segments 716A. After the staples have been fired, the actuator 702 is rotated to release compression of the tissue between the anvil 716 and shoulder 718 and the knob 719 is rotated to move the expander 717 distally thereby causing the anvil segments 716A to move to the collapsed position. The anvil 716 and rod 712 are then removed from the graft 760 and the other end of the graft 760 is attached to another body structure, such as an aorta or a coronary artery, thereby completing the graft procedure.

It will be understood that the foregoing is only illustrative of the principles of the present invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. For example, the particular stapler structural configurations shown are not critical and other configurations can be used if desired. One possible alternative for the configuration illustrated in FIG. 17 is to have a vessel rod that is retractable (e.g., by means of a telescoping rod). In addition, the vessel rod of this alternative embodiment can be curved to facilitate the anastomotic procedure if necessary. Also, the structure and method of the present invention can be employed thoracoscopically.

WHAT IS CLAIMED IS:

1. A method of attaching a graft to a body structure comprising the steps of:
  - 5 providing a stapler having an anvil, a rod, a staple pusher and a shoulder, the anvil being attached to the rod and the staple pusher being configured to drive staples, the shoulder being positioned opposite the anvil;
  - positioning the rod in a graft;
  - 10 everting the end of the graft around the shoulder;
  - inserting the anvil through an opening in a body structure to which the graft is to be stapled;
  - compressing the graft and the body structure between the anvil and the shoulder; and
  - 15 moving the staple pusher so that the staple pusher engages the staples and drives the staples against the anvil thereby stapling the graft to the body structure.
2. The method of claim 1, wherein:
  - 20 the compressing and firing steps are independent of one another.
3. The method of claim 1, wherein:
  - 25 the compressing step is carried out by moving the anvil.
4. The method of claim 1, wherein:
  - the providing step is carried out with the anvil having a plurality of segments, the segments being movable
  - 30 between an expanded shape and a compressed shape.
5. The method of claim 4, further comprising the step of:
  - 35 expanding the anvil segments from the expanded shape to the compressed shape after the moving step.

6. The method of claim 5, wherein:

the providing step is carried out with the stapler having an expander longitudinally movable with respect to the plurality of segments;

5 the expanding step being carried out by moving the expander longitudinally to engage and expand the anvil segments.

10 7. A method of attaching a graft to a body structure, comprising the steps of:

providing a stapler having a rod, a plurality of anvil segments, a movable staple pusher and a shoulder, each of the plurality of anvil segments having a recess adapted to deform a staple, the staple pusher being configured to drive a plurality of staples toward the recesses of the plurality of anvil segments, the shoulder being positioned opposite the anvil, the plurality of anvil segments being mounted to the rod and being movable between an expanded position and a collapsed position;

20 positioning the rod in a graft;  
everting an end of the graft around the shoulder;  
inserting the plurality of anvil segments through an opening in a body structure to which the graft is to be stapled, the plurality of anvil segments being inserted into the body structure in the collapsed position;

25 compressing the graft and the body structure between the plurality of anvil segments and the shoulder;  
expanding the plurality of anvil segments to the expanded shape;

30 moving the staple pusher so that the staple pusher engages the staples and drives the staples against the plurality of anvil segments;

collapsing the plurality of anvil segments from the expanded shape to the collapsed shape after the moving step;  
35 and

removing the rod from the graft when after the collapsing step.

8. The method of claim 7, wherein:

the providing step is carried out with the stapler having an expander, the expander being slidably coupled to the plurality of anvil segments for moving the plurality of anvil segments between the expanded and collapsed positions.

9. The method of claim 8, wherein:

the compressing and moving steps are performed independently.

10. A stapler for stapling a graft to a body structure, comprising:

a handle;

a housing coupled to the handle, the housing having a shoulder;

a staple pusher movably coupled to the housing;

a rod coupled to the handle and extending at least partially through the housing;

an anvil connected to the rod;

a first actuator configured to move the anvil relative to the shoulder of the housing for compressing tissue layers positioned therebetween;

a second actuator coupled to the handle, the second actuator being configured to drive the staple pusher for driving staples toward the anvil.

11. The stapler of claim 10, wherein:

the staple pusher includes a plurality of staple drivers for driving a plurality of staples.

12. The stapler of claim 10, wherein:

the anvil is separated into a plurality of anvil segments, the plurality of anvil segments being movable between an expanded position and a collapsed position.

13. The stapler of claim 12, further comprising:  
an expander slidably coupled to the handle, the  
expander slidably engaging the plurality of anvil segments for  
moving the plurality of anvil segments between the expanded  
and collapsed positions.

14. The stapler of claim 12, wherein:  
the plurality of anvil segments each include a  
recess for engaging and deforming a staple, the plurality of  
anvil segments having a smaller cross-sectional area when in  
the collapsed position than the recesses of the plurality of  
anvil segments when the plurality of anvil segments are in the  
expanded position for facilitating withdrawal of the anvil  
from a stapled area.

15. A staple for use in securing a body structure  
to another body structure, the staple comprising:  
a first leg having a first sharp end;  
a second leg having a second sharp end;  
a tissue compression portion extending between the  
first and second legs;  
a top coupled to the tissue compression portion, a  
first distance between the top and the tissue compression  
portion being at least 15 % of a second distance between the  
top and the first and second sharp ends.

16. The staple of claim 15, wherein:  
the first distance is at least 30 % of the second  
distance.

17. The staple of claim 15, wherein:  
the first and second legs each include a notch, the  
first and second legs bending at the notch when the staple is  
fired.

18. The staple of claim 15, wherein the staple is  
solid between the top and tissue compression portion.

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FIG. 1

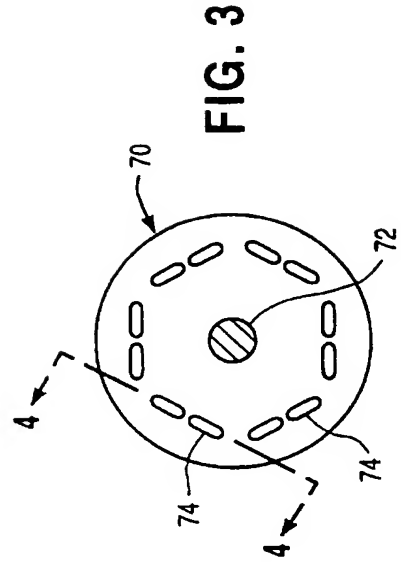
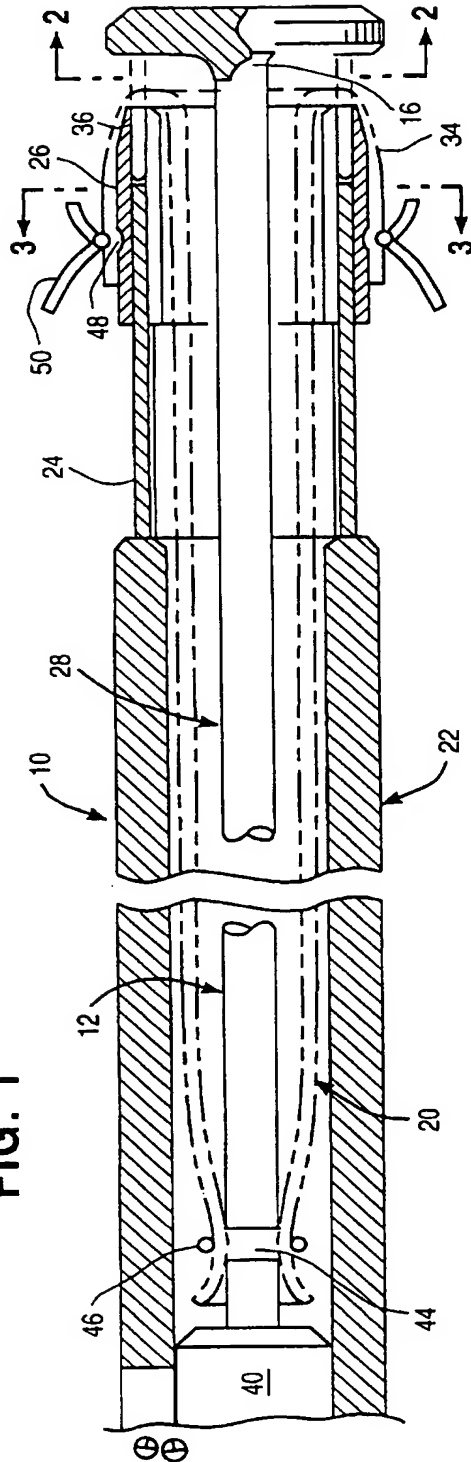


FIG. 3

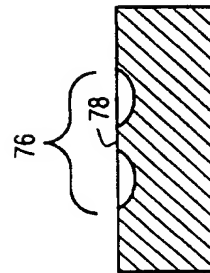


FIG. 4

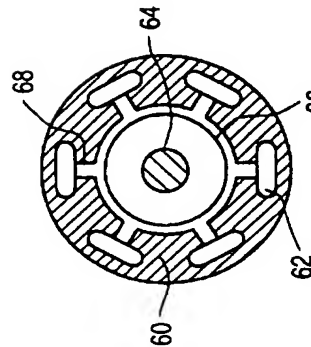
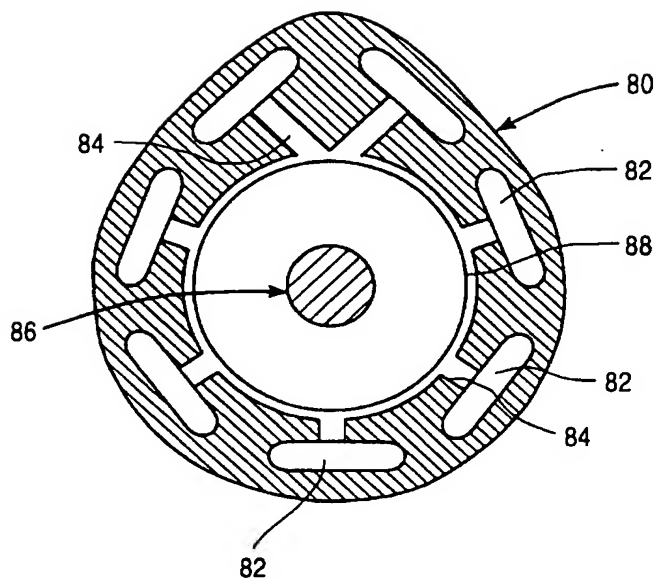


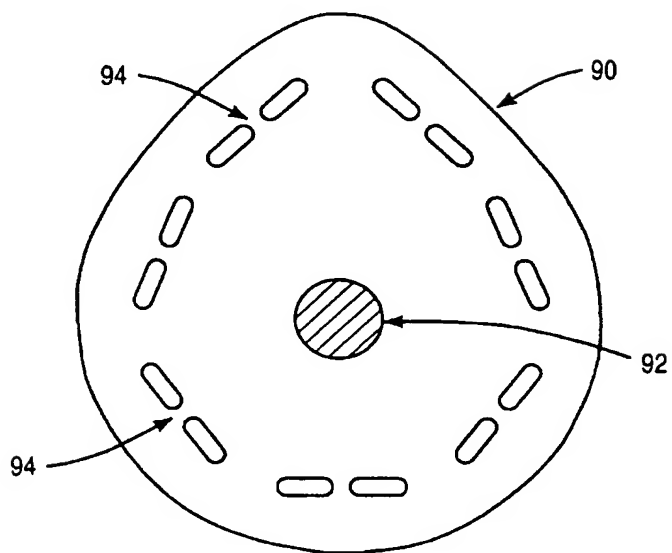
FIG. 2

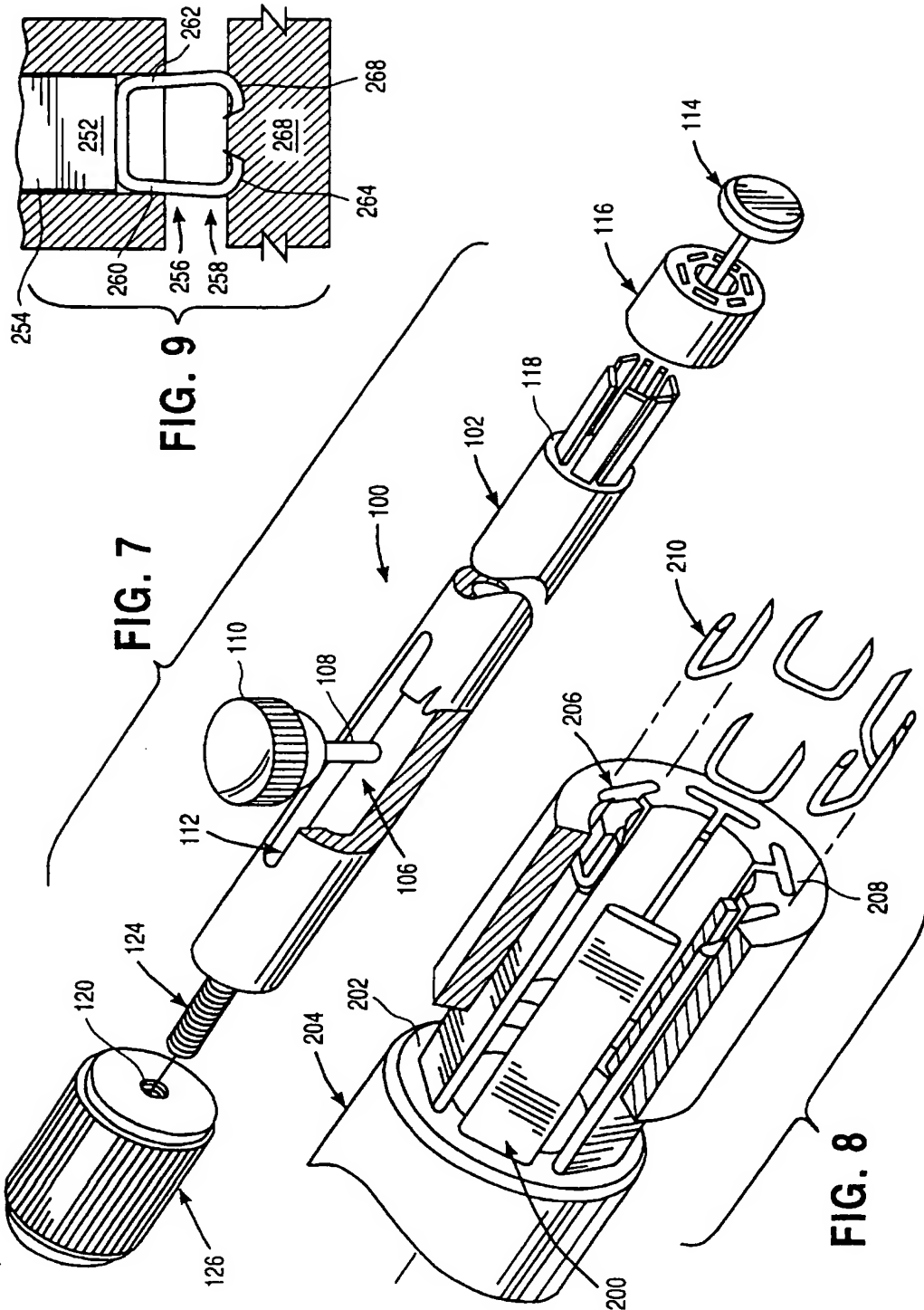
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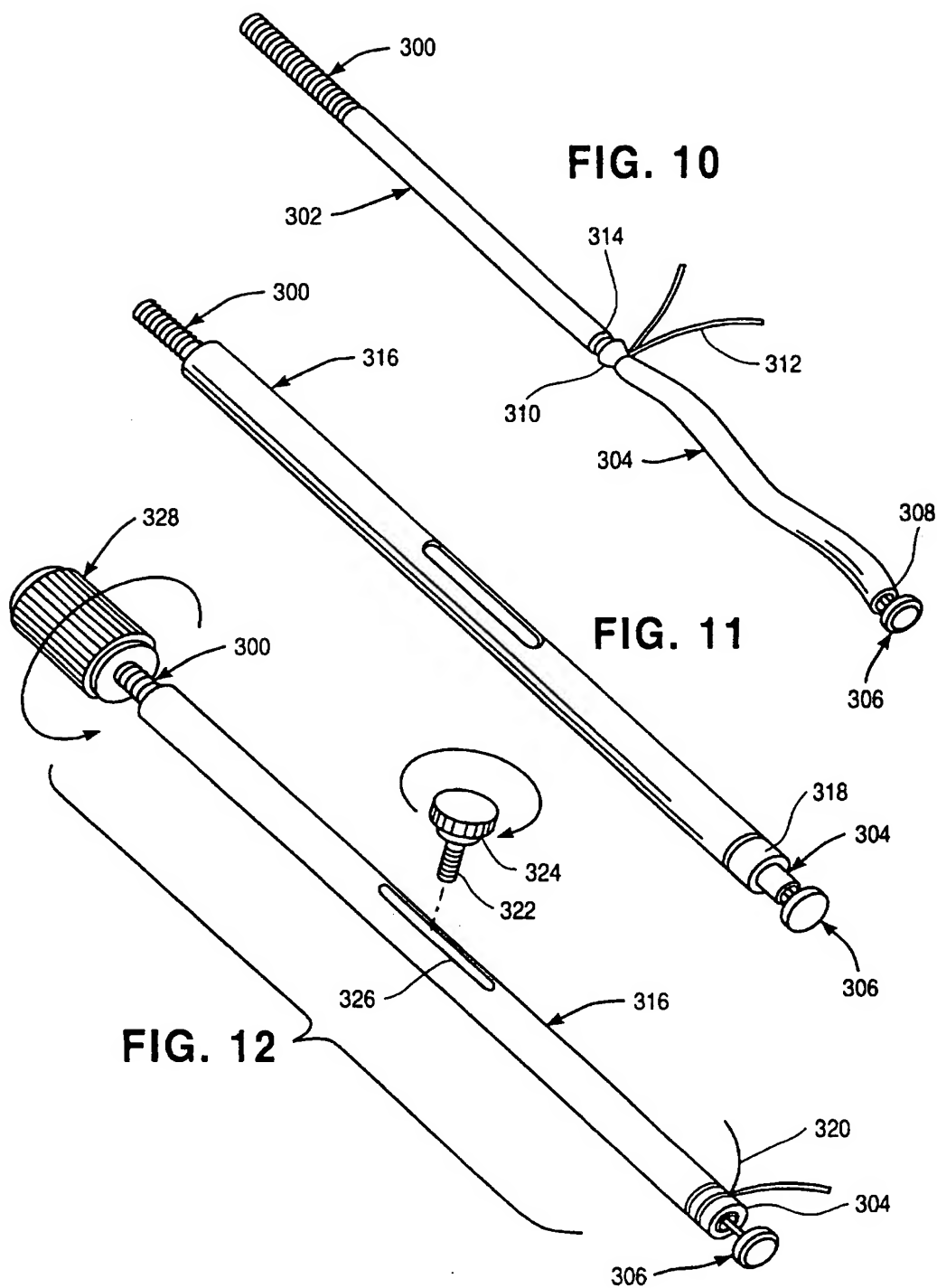


**FIG. 5**

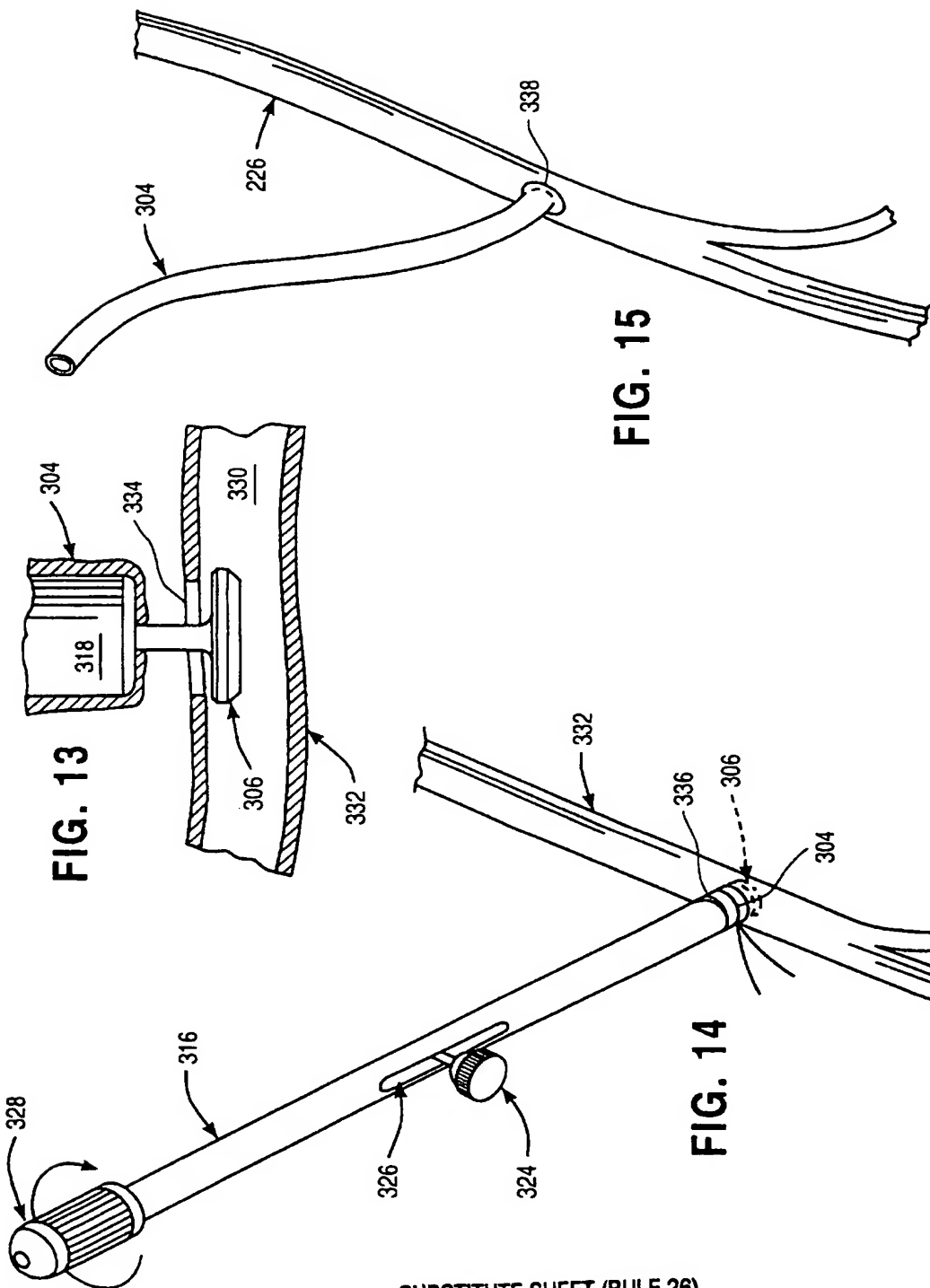
**FIG. 6**







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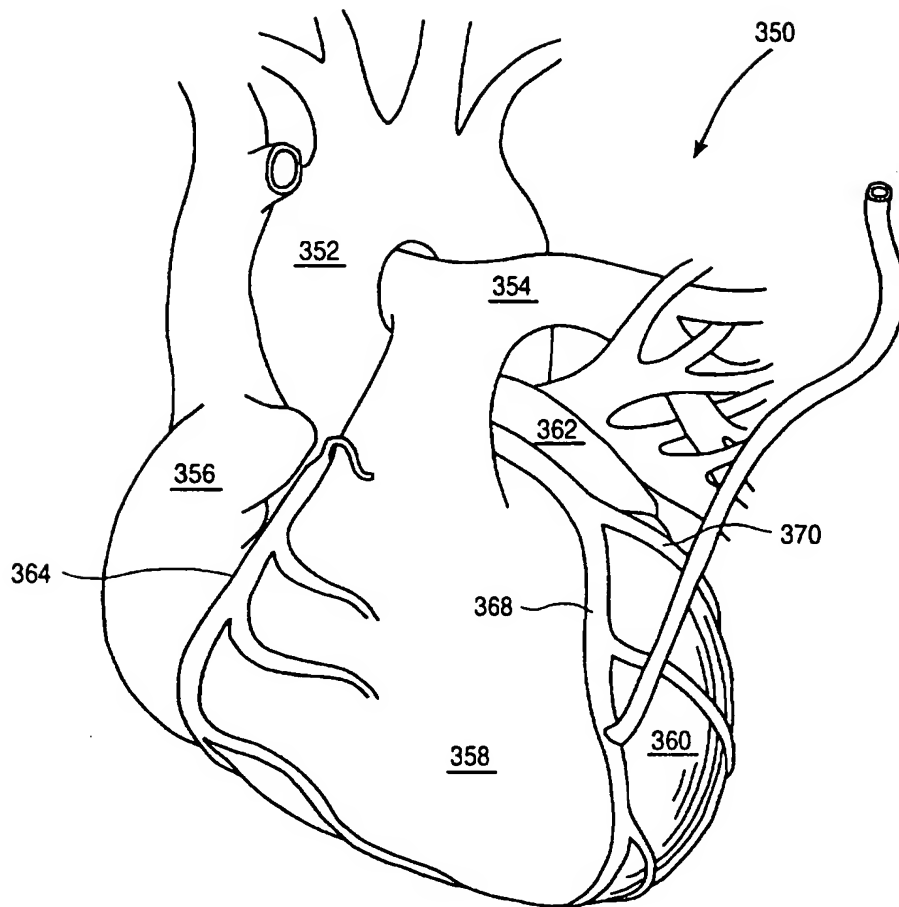
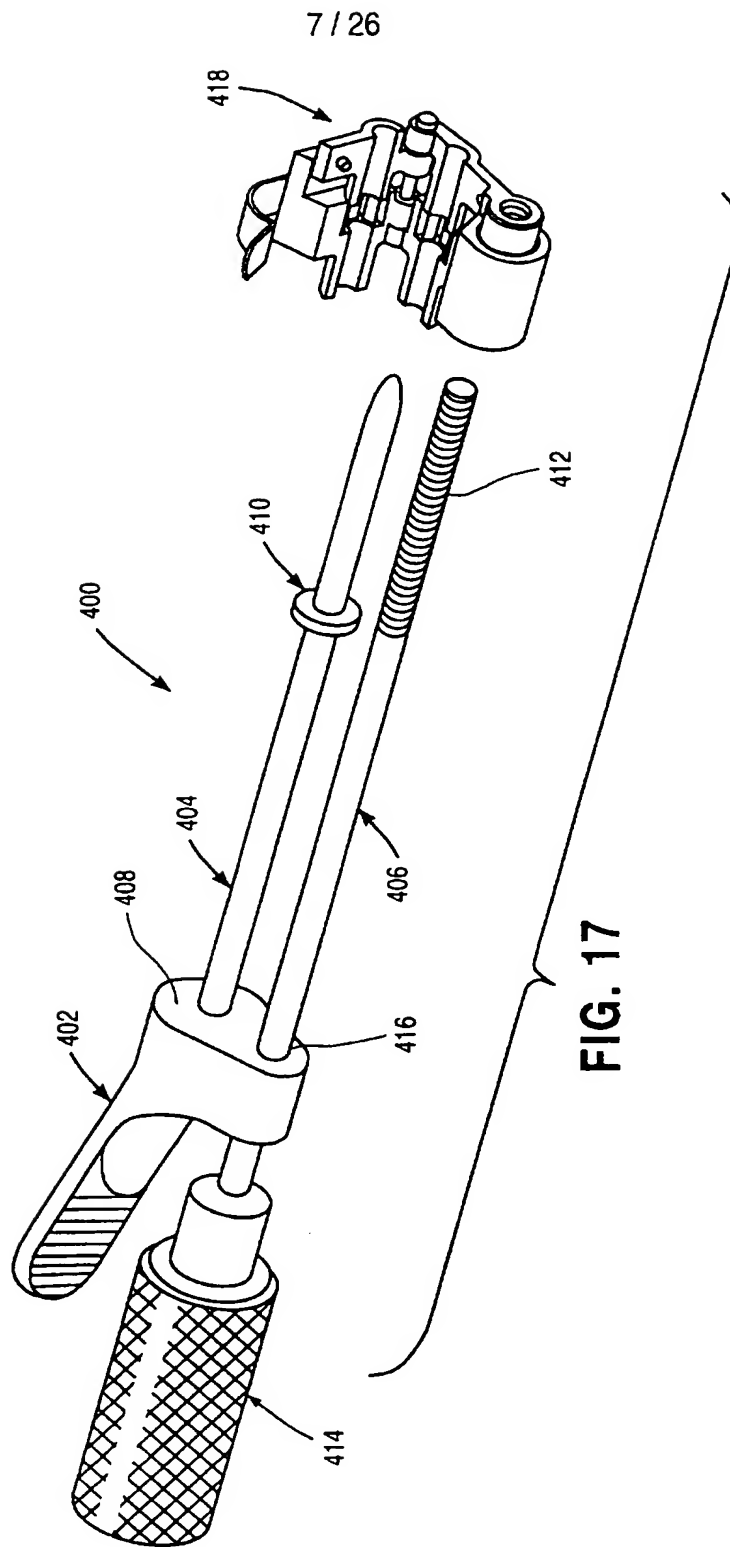


FIG. 16



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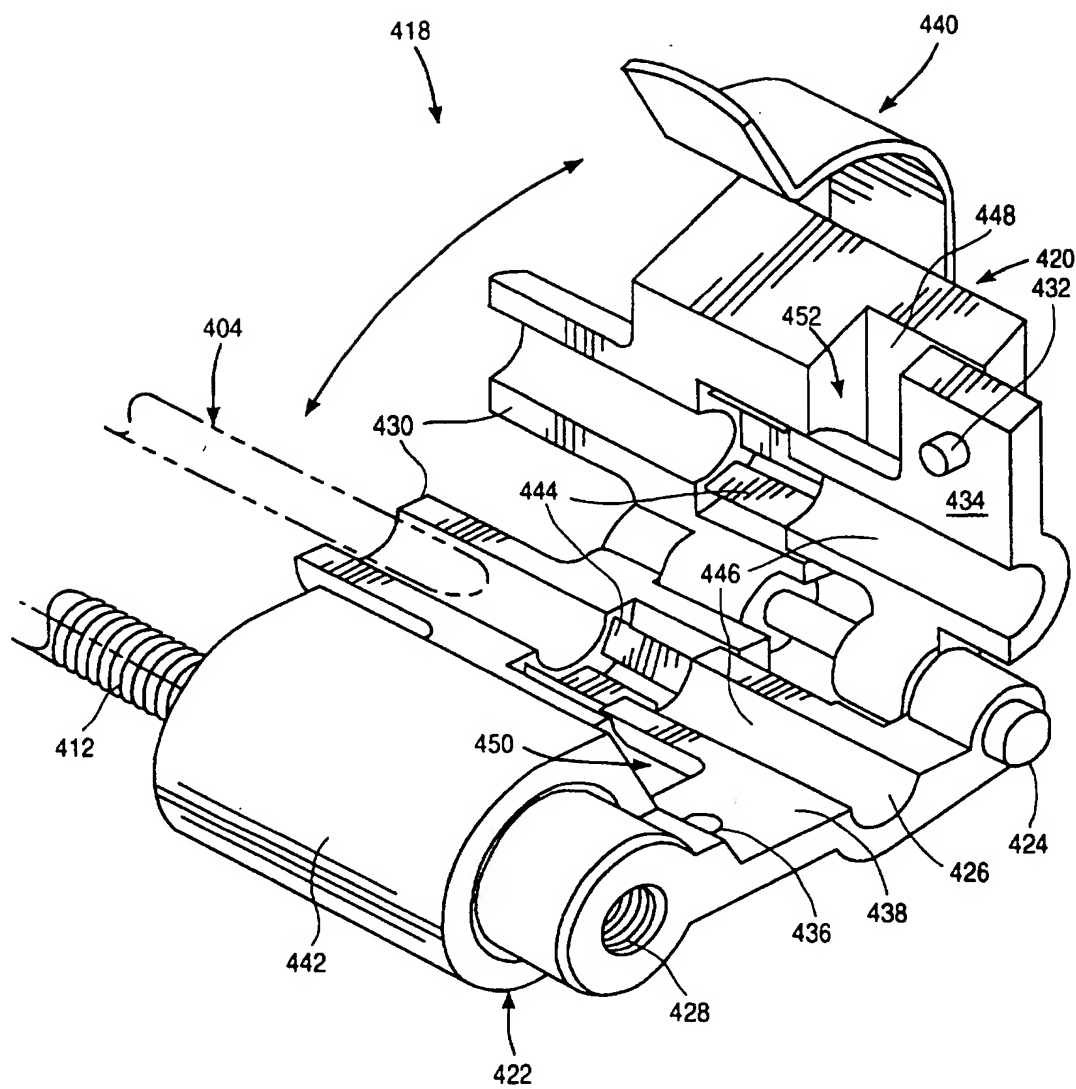
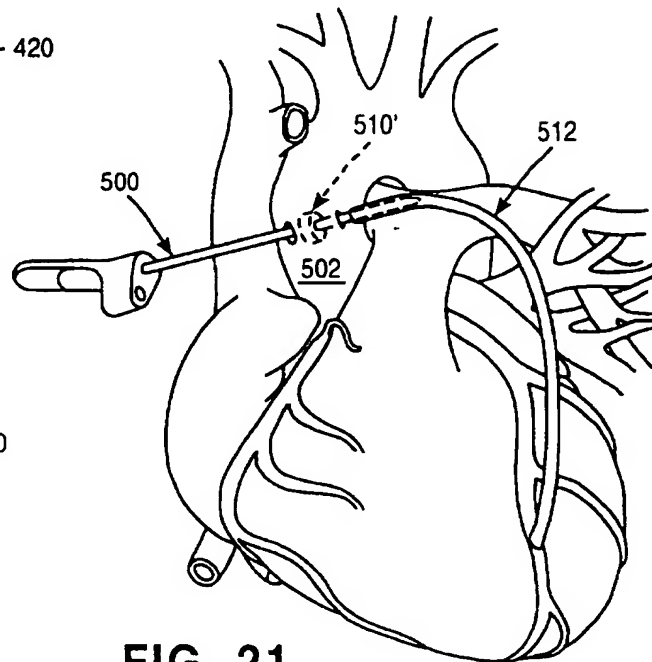
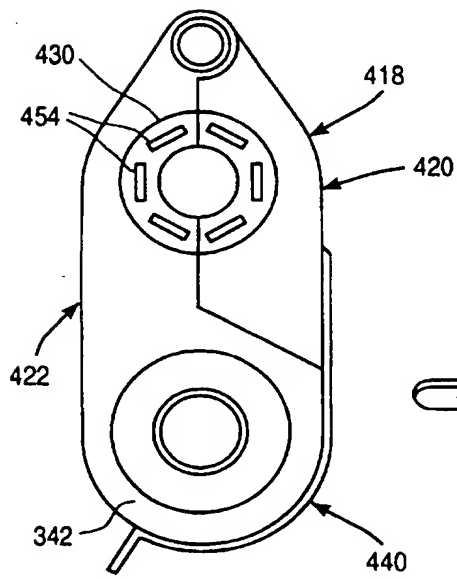
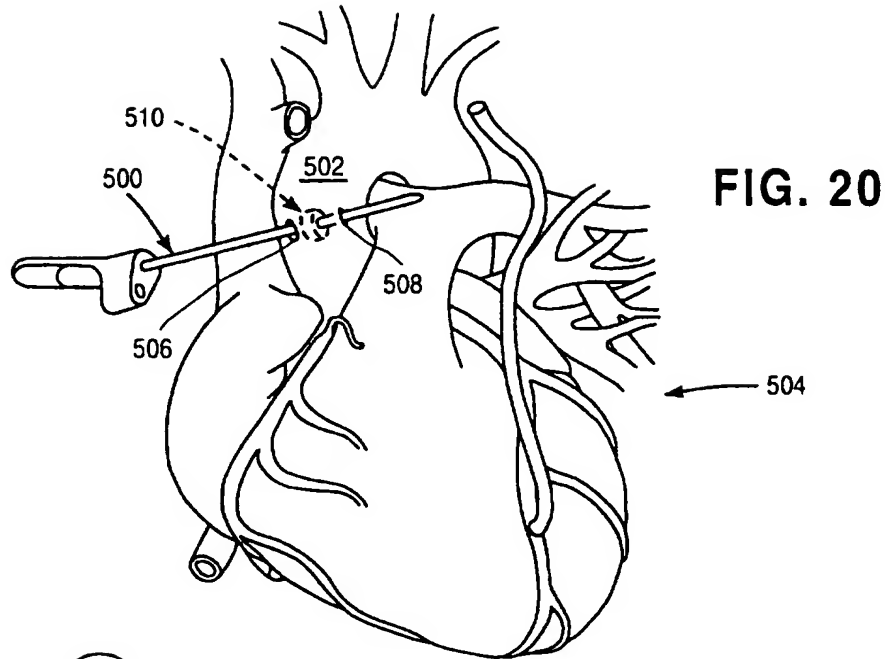


FIG. 18

SUBSTITUTE SHEET (RULE 26)

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FIG. 22

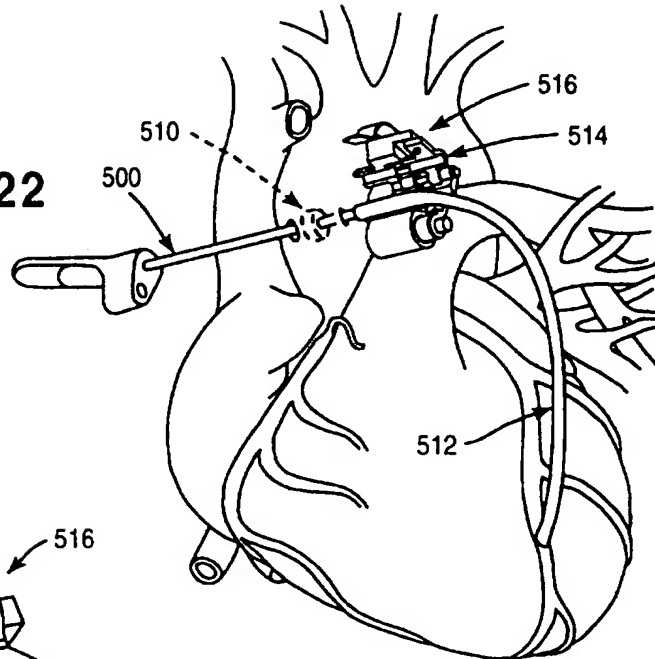


FIG. 23

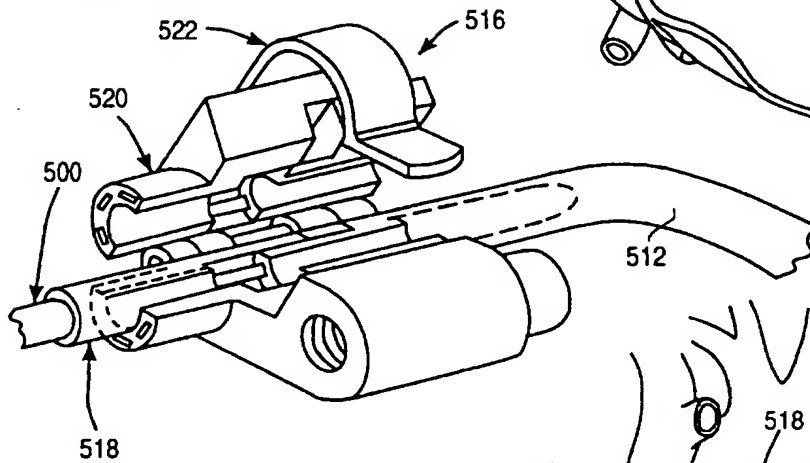
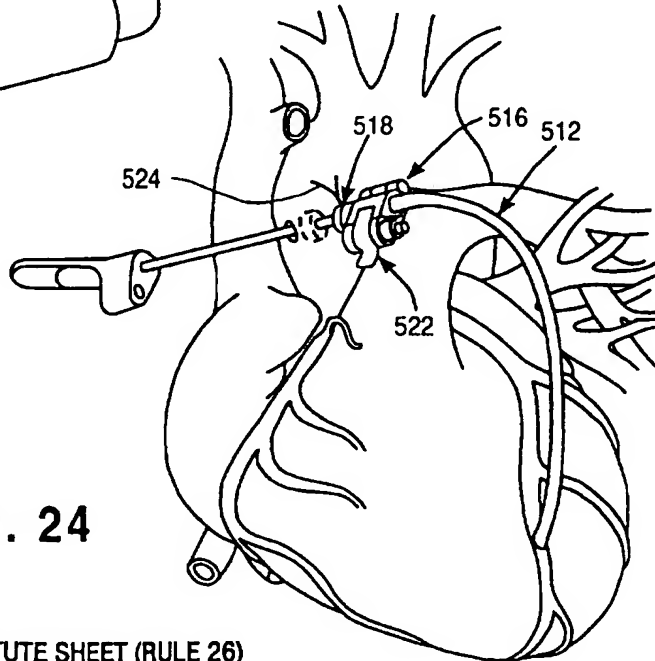
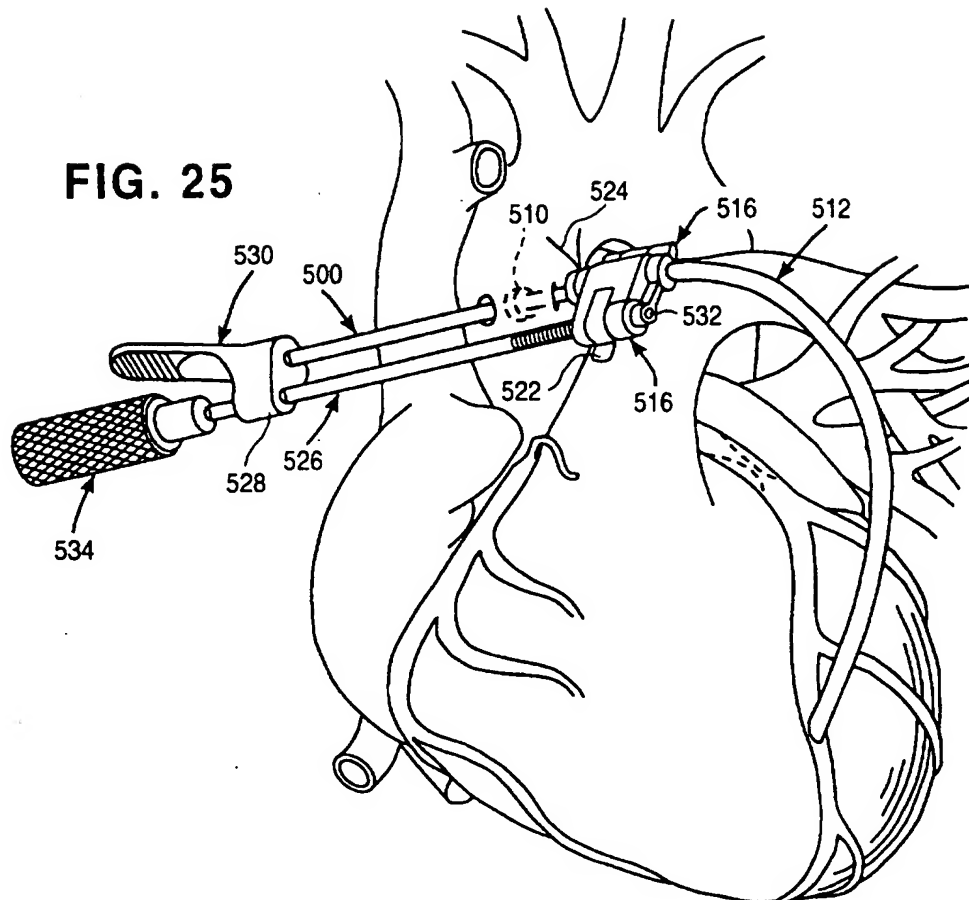


FIG. 24

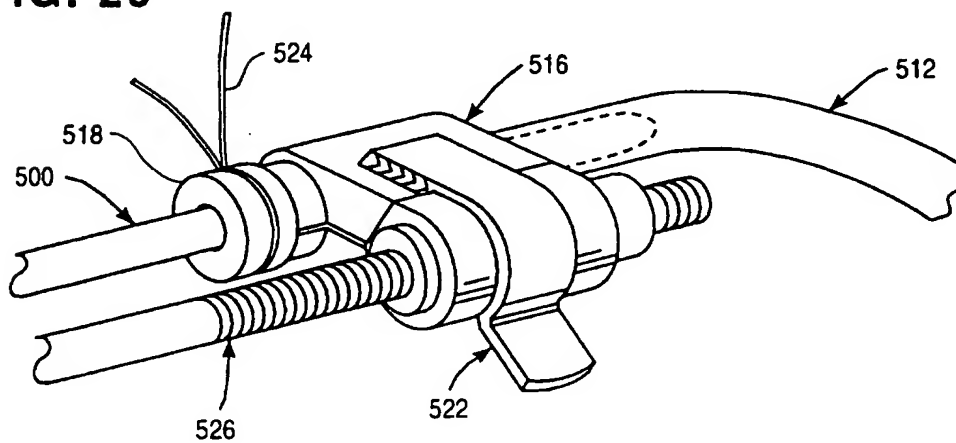


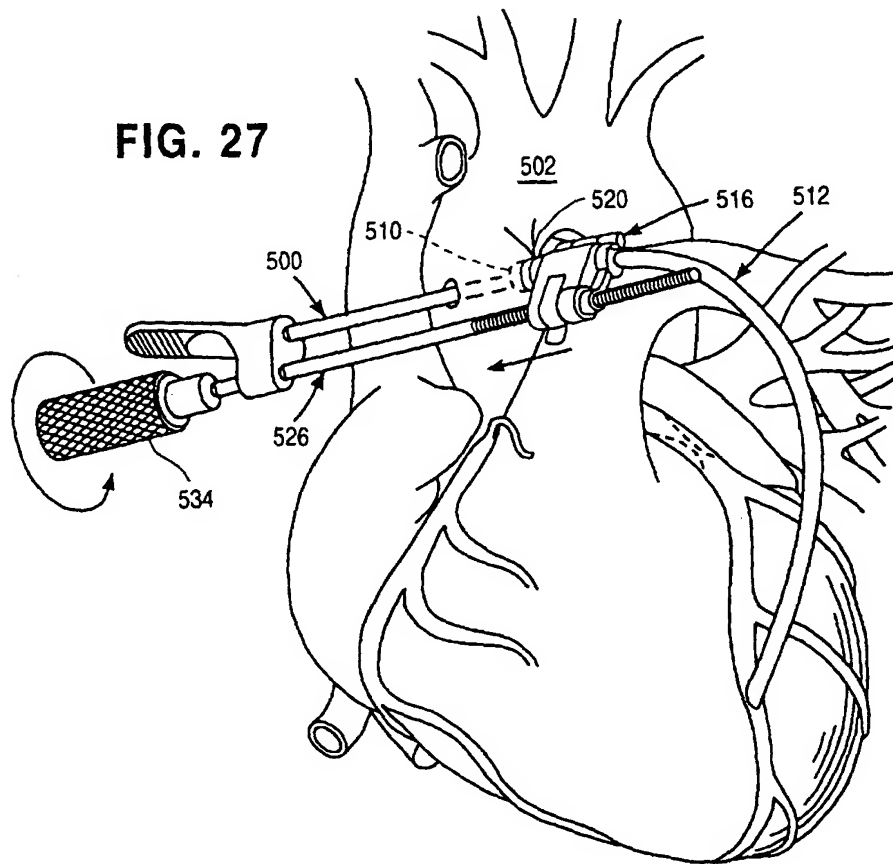
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**FIG. 25**



**FIG. 26**





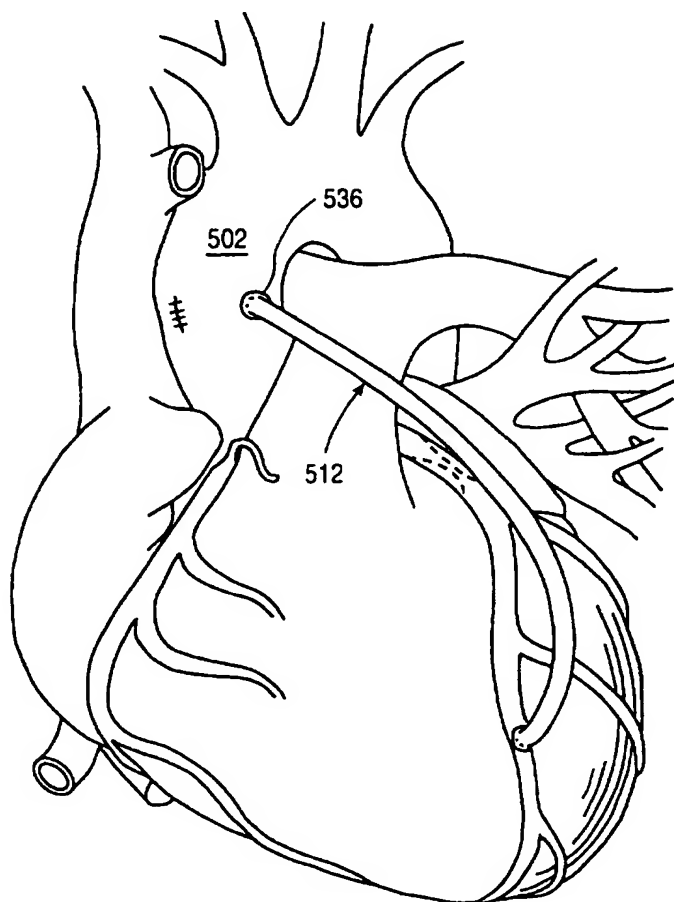
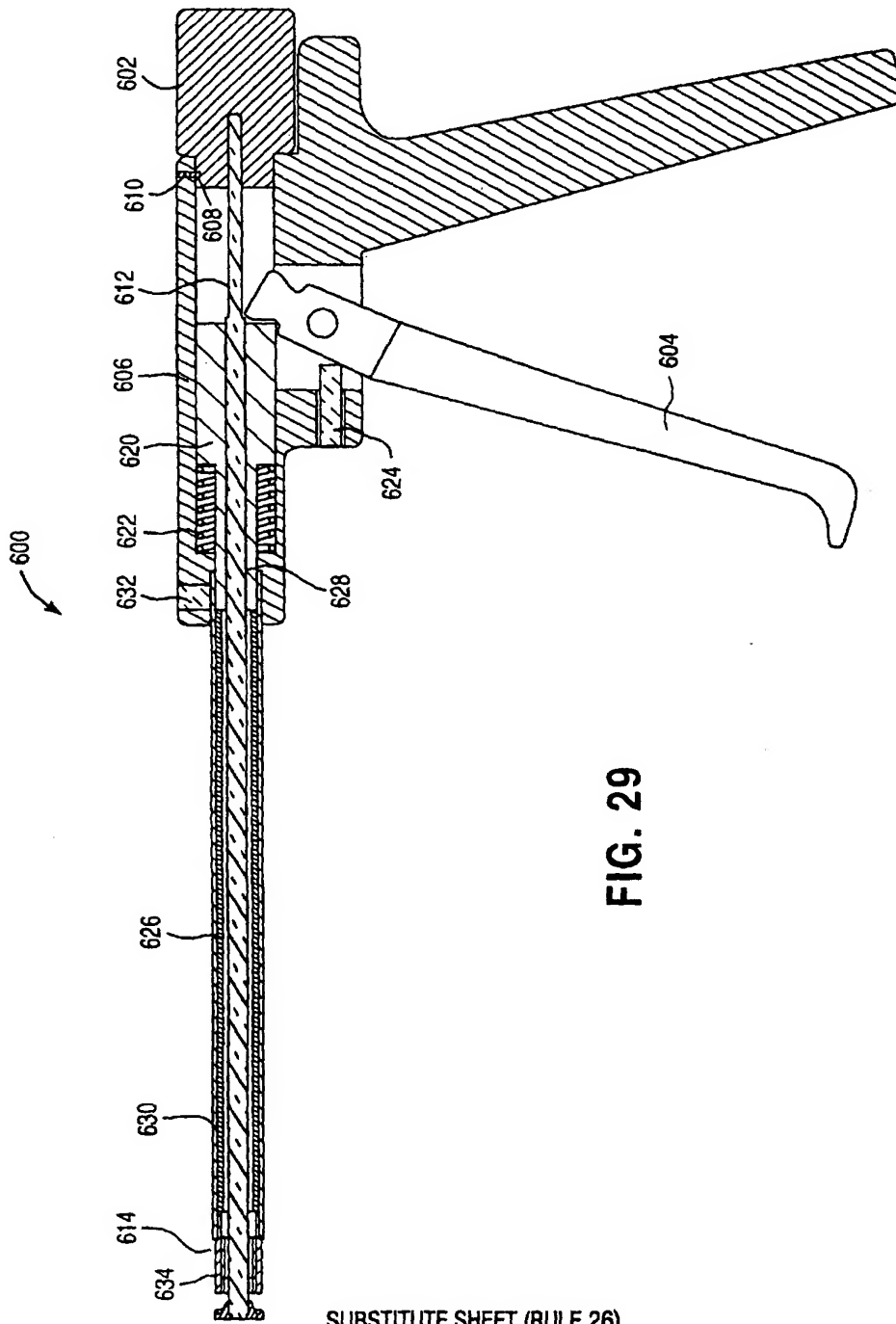


FIG. 28

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SUBSTITUTE SHEET (RULE 26)

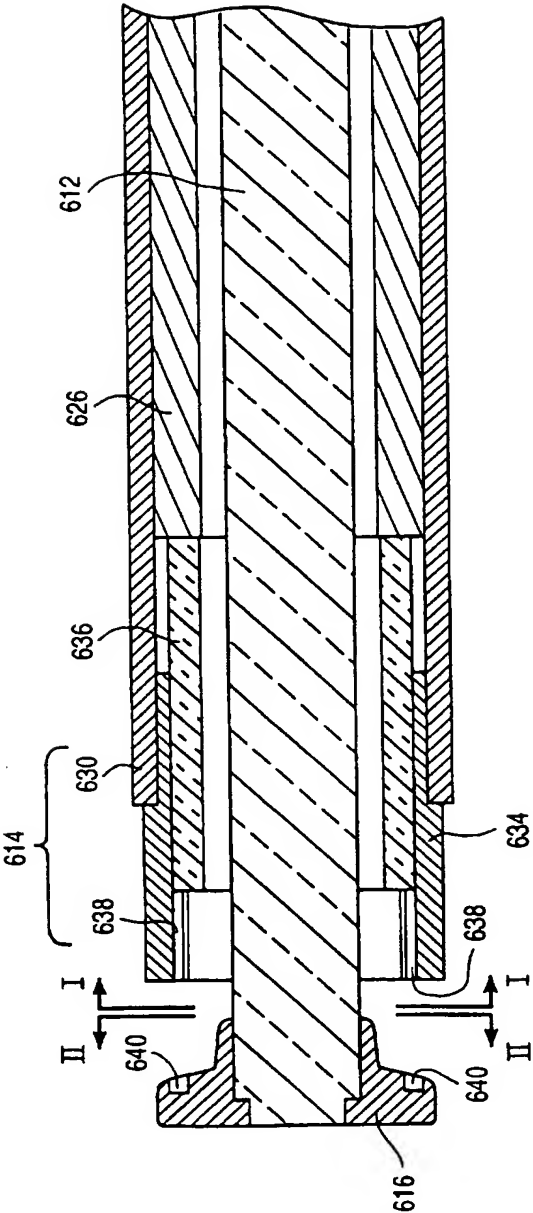


FIG. 30

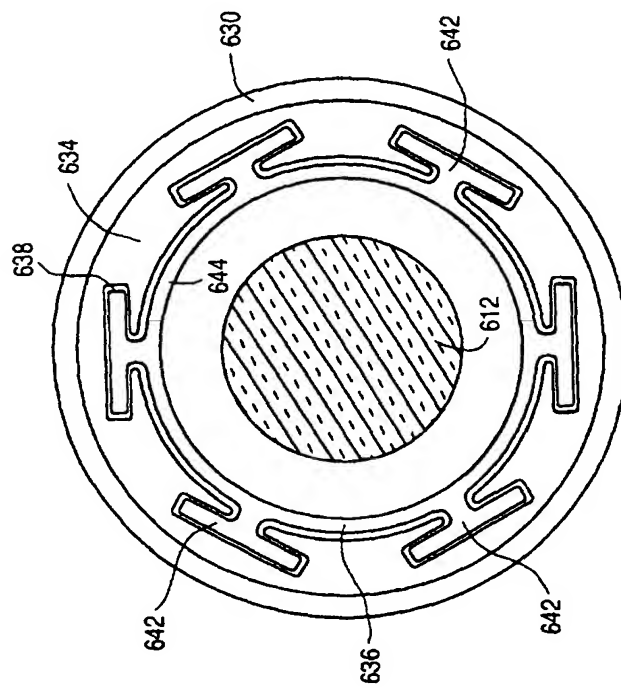


FIG. 31

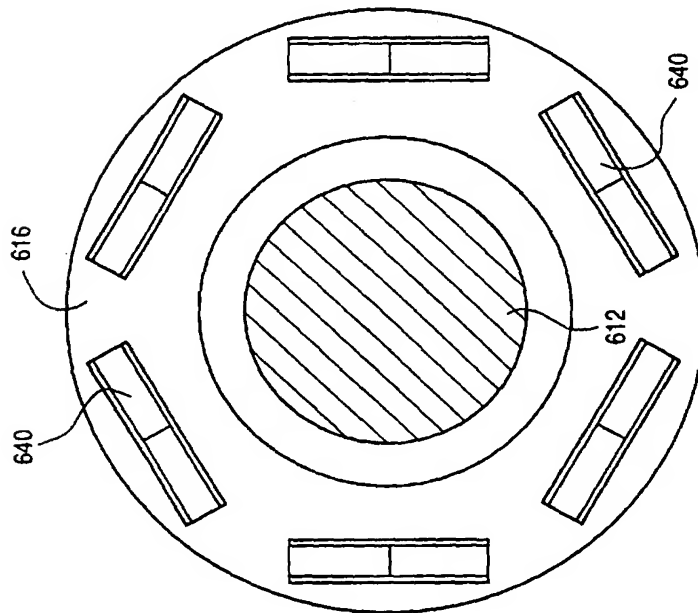


FIG. 32

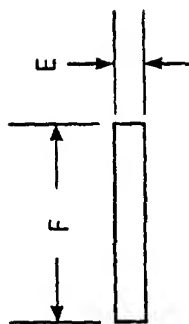


FIG. 34

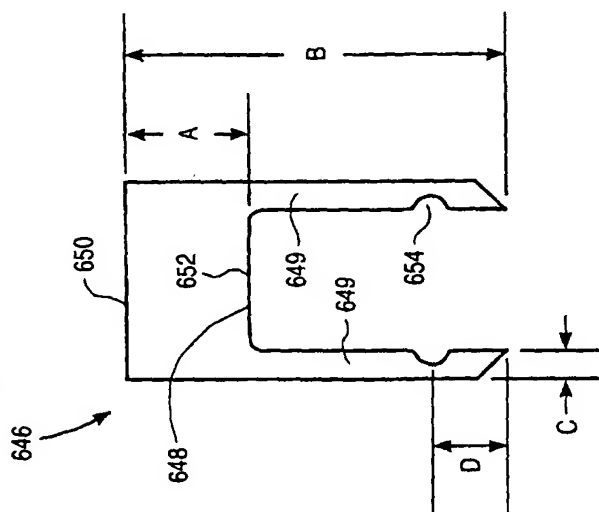


FIG. 33

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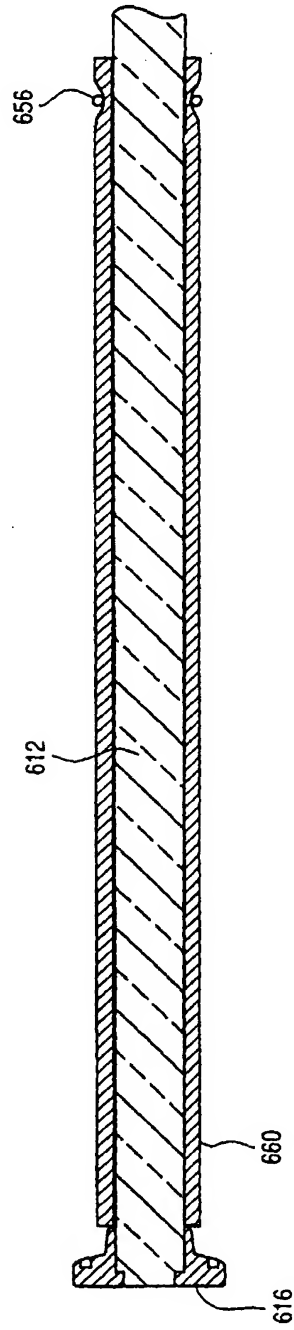


FIG. 35

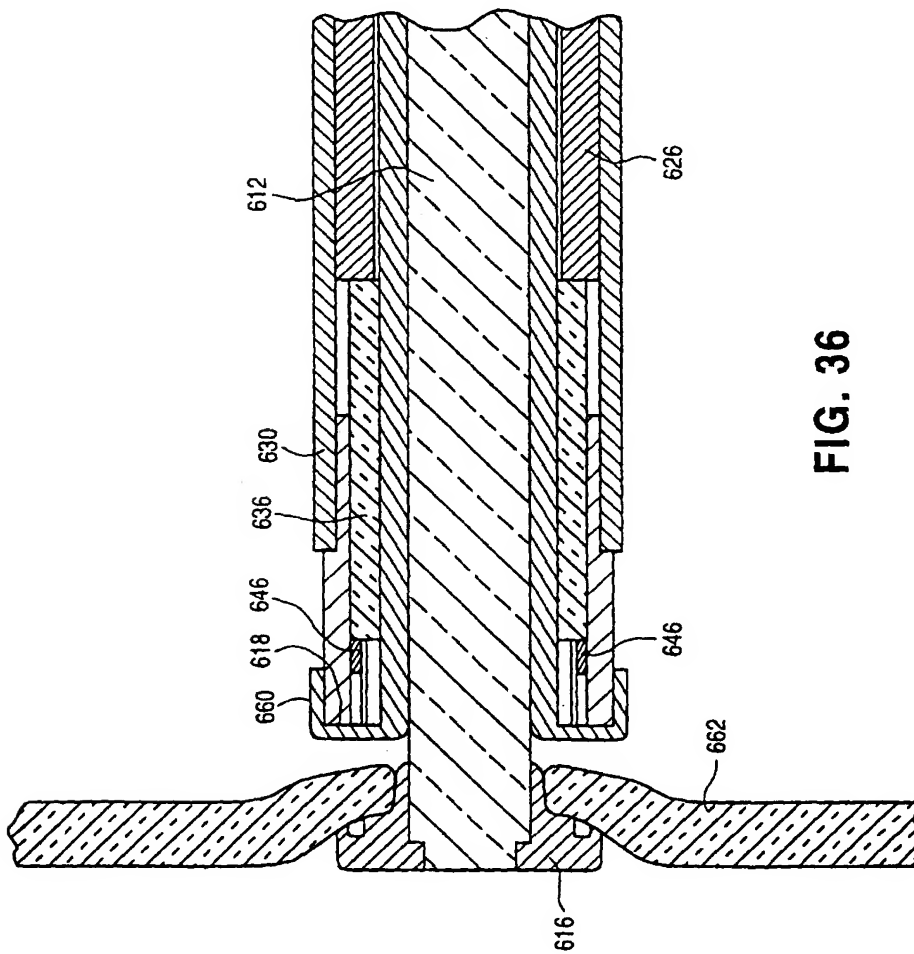


FIG. 36

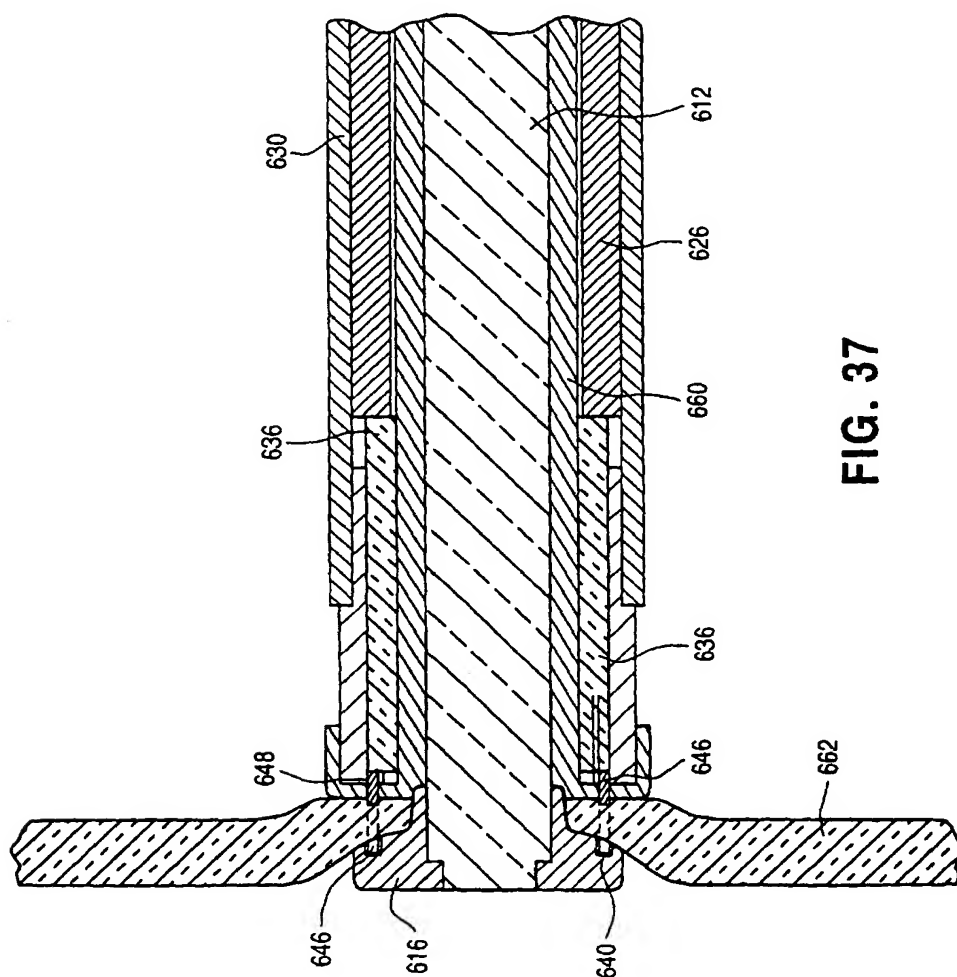


FIG. 37

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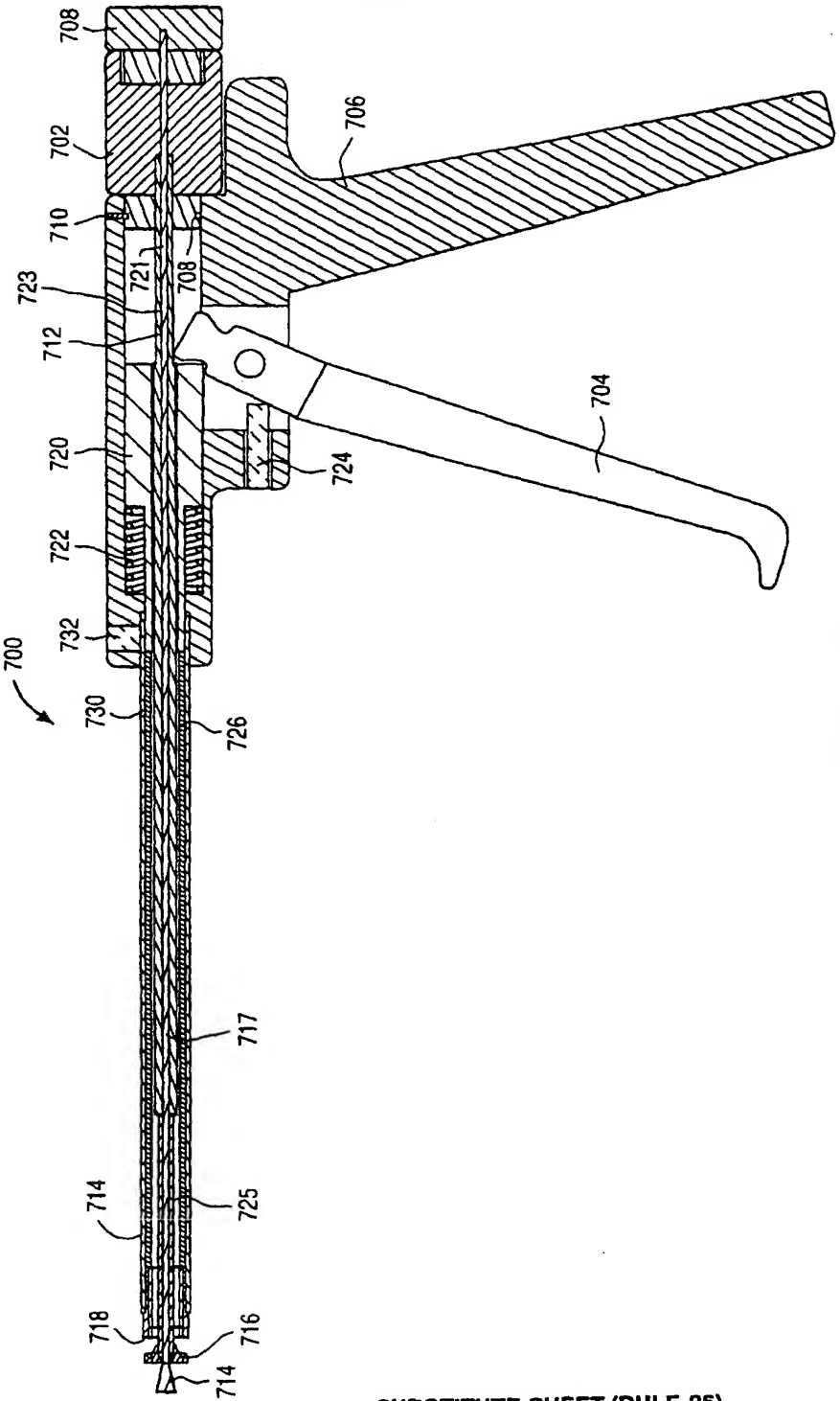
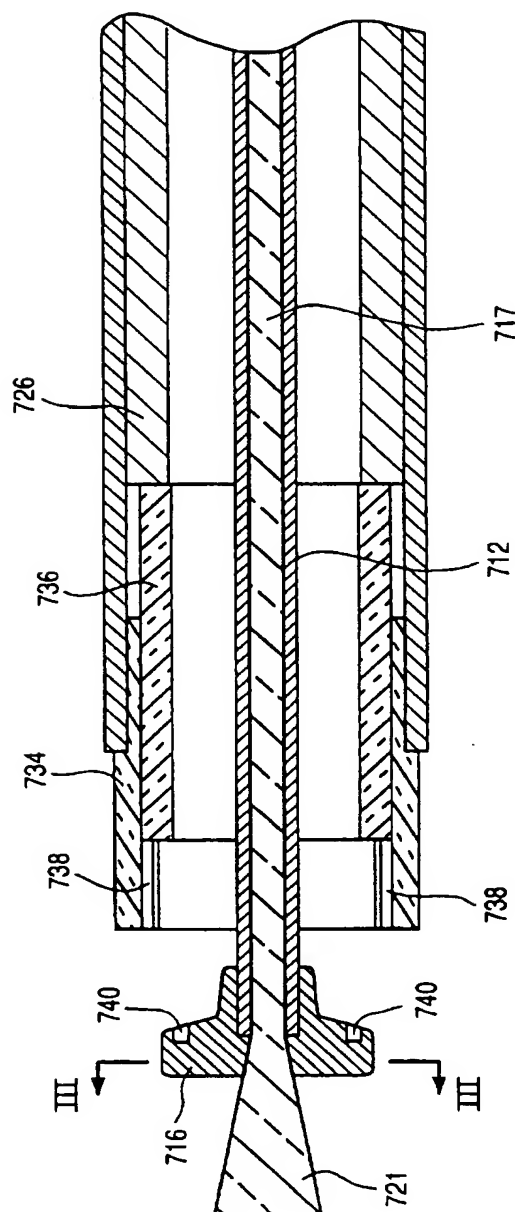


FIG. 38



**FIG. 39**

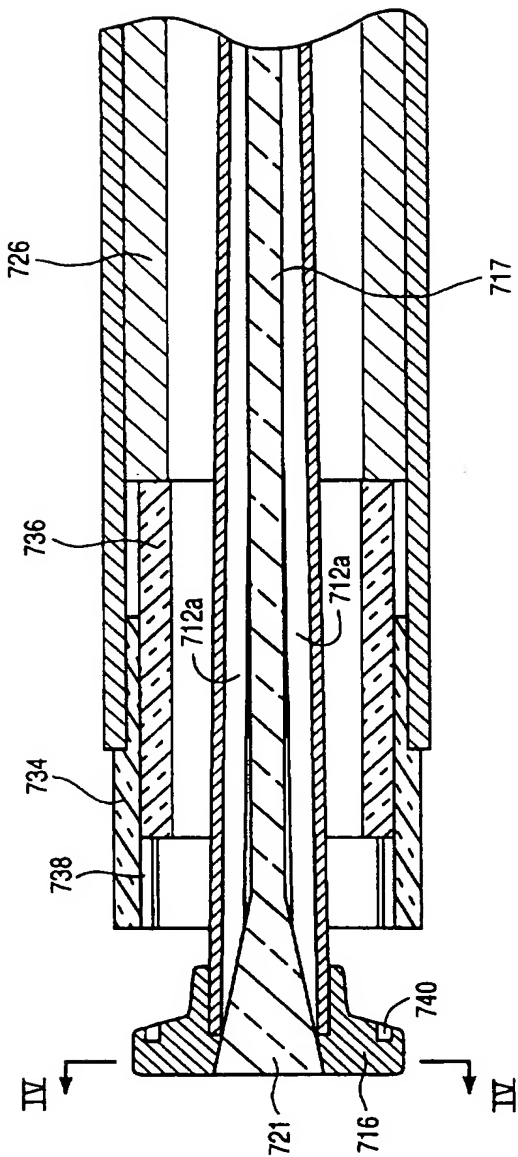


FIG. 40

**FIG. 41**

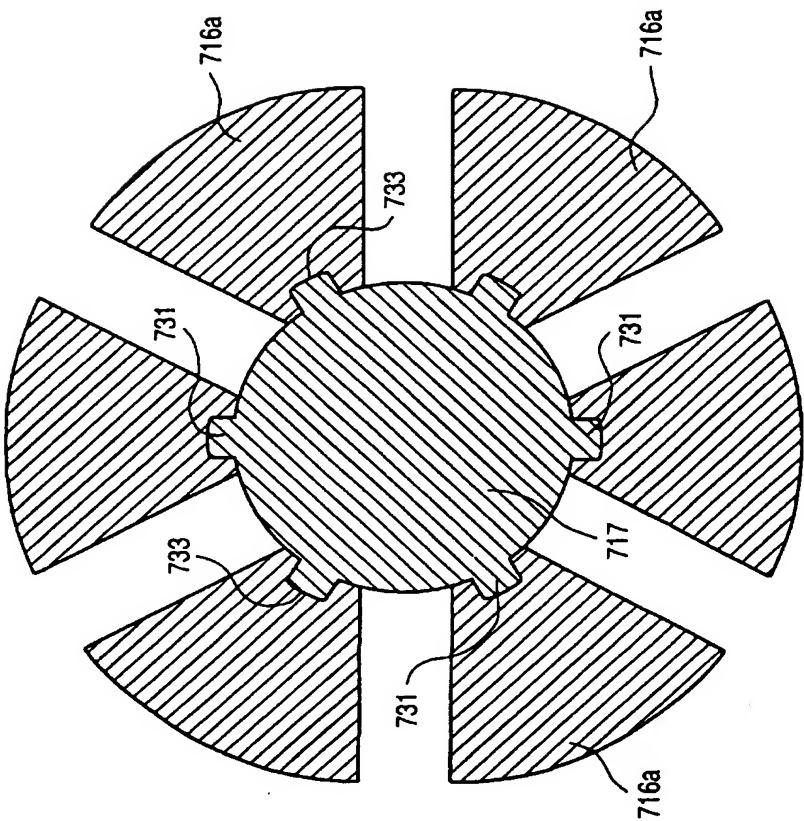


FIG. 42

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US97/01579

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) : A61B 17/068

US CL : 227/19, 175.1, 179.1 606/219

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 227/19, 175.1, 179.1; 606/219

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4,505,414 (FILIPPI) 19 March 1985, See Entire Document.	10-14
A	US, A, 4,592,354 (ROTHFUSS) 03 June 1986, See Entire Document.	1-14
A	US, A, 4,700,703 (RESNICK ET AL.) 20 October 1987, See entire Document.	1-14
A	US, A, 5,292,053 (BILOTTI ET AL.) 08 March 1994, See Entire	1-14
A	US, A, 5,403,333 (KASTER ET AL.) 04 April 1995, See Entire Document.	1-14

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A* document defining the general state of the art which is not considered to be of particular relevance	*X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*E* earlier document published on or after the international filing date	*Y*	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z*	document member of the same patent family
*O* document referring to an oral disclosure, use, exhibition or other means		
*P* document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

02 MAY 1997

Date of mailing of the international search report

02 JUN 1997

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Commissioner of Patents and Trademarks  
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Washington, D.C. 20231

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Authorized officer

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Paralegal Specialist  
Group 3200

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US97/01579

### BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

Group I, claims 1-14, is drawn to surgical method and apparatus and has the special technical feature of an expandable and collapsible anvil.

Group II, claims 15-18, is drawn to a surgical staple and has the special technical feature of a wide crown portion and legs extending therefrom.

Group I does not have the special technical feature of Group II, and Group II does not have the special technical feature of Group I.

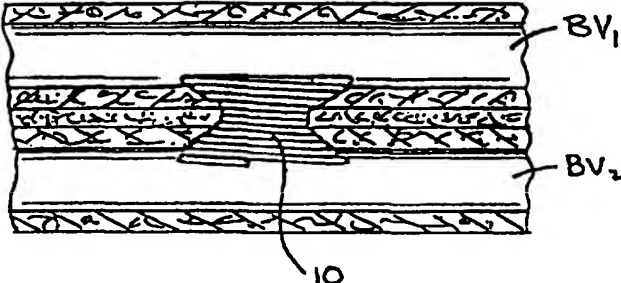
PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau



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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : A61M 29/00		A1	(11) International Publication Number: WO 97/27898
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(54) Title: METHODS AND APPARATUS FOR CONNECTING OPENINGS FORMED IN ADJACENT BLOOD VESSELS OR OTHER ANATOMICAL STRUCTURES			
(57) Abstract			
<p>This invention is methods and apparatus for connecting two anatomical passageways, such as blood vessels, in side-to-side fashion. Openings are formed in the sidewalls of the passageways, and a connector apparatus (10) of the present invention is implanted within such openings, and extends between the passageways or blood vessels (BV1, BV2) so as to connect the passageways or blood vessels (BV1, BV2) such that the openings are held in direct alignment with one another, thereby allowing body fluids to pass from one passageway into the other.</p>			

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**METHODS AND APPARATUS FOR CONNECTING OPENINGS FORMED IN  
ADJACENT BLOOD VESSELS OR OTHER ANATOMICAL STRUCTURES**

**Related Applications**

5        This patent application claims priority to United  
States Provisional Patent Application Serial No.  
60/010,614, filed on February 2, 1996, and is a  
continuation-in-part of co-pending United States Patent  
Applications 08/730,327, filed on October 11, 1996 and  
10    08/730,496, filed on October 11, 1996, the entire  
disclosure of each such related application being  
expressly incorporated herein by reference.

**Field of the Invention**

15        The present invention relates generally to medical  
devices, and more particularly to methods and apparatus  
for making connections between blood vessels or other  
adjacently situated anatomical or synthetic structures  
having hollow lumens or cavities formed therein.

20

**Background of the Invention**

      In modern medical practice, it is often desirable  
to form connections between adjacent anatomical  
passageways, or between adjacent segments of a single  
25    anatomical passageway. The types of anatomical  
passageways between which such connections may be made  
include; blood vessels, vas deferens, fallopian tubes,  
intestines, lymphatic ducts, grafts, ventricular  
cavities of the heart or brain, etc.

30        Recently, applicant has devised certain in situ  
vascular bypass procedures wherein blood flow  
passageways (e.g., puncture tracts or interstitial  
tunnels) are formed between the lumens adjacently  
situated blood vessels (e.g., between an obstructed  
35    coronary artery and an adjacent coronary vein) to  
bypass a diseased, injured or obstructed segment of one  
blood vessel. These procedures have previously been

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described in United States Patent Application Serial  
Nos. 08/730,327 and 08/730,496. Also, Provisional  
United States Patent Application Serial No. 60/010,614  
particularly describes certain minimally invasive  
5 vascular grafting procedures devised by applicant for  
by-passing an obstructed artery. In these grafting  
procedures, a tubular graft (e.g., a segment of an  
endogenous blood vessel or a tube graft formed of  
natural or synthetic material) is maneuvered into  
10 juxtaposition with the obstructed artery. One or more  
openings are formed in the graft and the adjacent  
artery. The openings formed in the graft are then  
connected to the openings formed in the artery, such  
that blood may flow between the graft and the artery.  
15 Additionally, various procedures have been  
reported by others wherein implantable apparatus are  
used to connect or facilitate flow of bodily fluid  
between anatomical passageways (e.g., genitourinary  
ducts). One such procedure is described in United  
20 States Patent No. 3,042,021 (Read) entitled BYPASS TYPE  
INSERT PLUG FOR BODY PASSAGEWAY.

To facilitate the connection of adjacently  
situated anatomical structures, as in the above-  
mentioned medical procedures, there exists a need in  
25 the art for the design and development of new connector  
apparatus which may be implanted, through transluminal  
catheters or probes, to form a secure connection  
between openings formed in adjacently situated  
anatomical structures and/or to maintain such openings  
30 in direct alignment and/or fluidic communication with  
each other.

#### Summary of the Invention

The present invention provides apparatus for  
35 connecting or joining a first opening formed in a first  
anatomical structure of the type having a hollow inner  
space or lumen (e.g., a blood vessel, a hollow organ, a

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chamber of the heart, a vascular graft, etc.) with a second opening formed in a second anatomical structure which also has a hollow innerspace of similar type. In general, these connecting apparatus comprise a) a first engagement member which is engageable with the first anatomical structure, b) a second engagement member which is engageable with the second anatomical structure, and c) a connecting portion which extends or traverses between the first and second engagement members, and serves to hold the openings formed in the first and second anatomical structures in the desired alignment, typically, such that fluid may pass from one anatomical structure into the other.

Further in accordance with the invention, the connecting apparatus may be initially deployable in a radially compact state such that it may be advanced transluminally through the body to a desired implantation site, and is subsequently transitionable to a radially expanded configuration wherein the first engagement member will engage the first anatomical structure and the second engagement member will engage the second anatomical structure. Additionally or alternatively, the first and second engagement members may be initially deployed in non-operative positions (e.g., extending generally parallel to the longitudinal axis of the apparatus) to facilitate transluminal passage and/or placement of the apparatus at the desired implantation site. Thereafter, the first and second engagement members may be transitionable to a second configuration (e.g., an outwardly splayed configuration) such that the first and second engagement members will engage the first and second anatomical structures, as desired. In this manner, the apparatus may be self expanding or self splaying (e.g., formed of resilient or shape memory material) such that the radial expansion or transitioning of the engagement members will occur when surrounding constraint (e.g.,

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constraint of a surrounding catheter wall) has been removed from the apparatus. Alternatively, the apparatus may be plastically deformable and provided with a pressure-exerting tool (e.g., a balloon) which  
5 will plastically deform the apparatus to cause the desired radial expansion and/or transitioning of the engagement members after the apparatus has been positioned in its desired implantation site.

Further in accordance with the invention, the  
10 engagement members may comprise wire loops, wire members, flanges, extensions, tongues, or any other suitable type of member which will embed into or otherwise engage the adjacent surface of an anatomical structure so as to hold the apparatus at its desired  
15 implantation site and/or to maintain the patency of the passageway as well as the length of the connection.

Still further in accordance with the invention, the connecting portion of the apparatus may comprise one or more elongate strands or members, a solid or  
20 perforated tube, or any other suitable connecting portion which will serve to link or connect the first and second engagement members and hold them at their desired spaced-apart distance. In some embodiments, the connecting portion may be elastic or biased so as  
25 to exert continual pulling force or retraction against the first and second engagement members. In other embodiments, the connecting portion may be rigid and non-elastic so as to remain at a fixed non-alterable length. Additionally, in some embodiments, the  
30 connecting portion may define a cylindrical or annular support member which will dilate, support or otherwise maintain any surrounding interstitial tissue in a desired configuration so as to prevent blockage or non-  
35 patency of the flow path formed between the first and second openings in the first and second anatomical structures.

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Additionally, the connecting portion may be constructed to maintain a minimum passageway diameter between the openings in the first and second anatomical structures. Also, the connecting portion may be  
5 constructed to perform some surface modeling or customization of the surrounding tissue as by mechanical pressure exertion, application of a coating or chemical treatment, xenograft, emission of energy, etc. In this manner, the delivery catheter or delivery  
10 system used to facilitate implantation of the correct connector apparatus may be equipped with wires, or other energy transmitting members which are in contact with the connector apparatus and which will deliver energy into the connector apparatus, thereby using the  
15 connector apparatus as an energy-transferring member for causing deburring, enlargement, scaring, or other modification of the surrounding tissue with which the connector member comes in contact. Examples of the types of energy which may be useable for this purpose  
20 include electrical energy, radiofrequency, ultrasound, radiation (e.g, beta, gamma, etc.), etc.

Still further in accordance with the invention, the connecting portion of the apparatus may be elastic, adjustable, telescoping, distensible or of accordion  
25 construction, etc., so as to adjust or conform to passageways of differing length. This aspect of the invention will allow a connector apparatus to be used for applications wherein the distance between the first and second openings in the first and second  
30 anatomical structures may vary and in each specific application, to maintain the first and second anatomical structures in relatively constant tension (i.e., constant force). Alternatively, for connector apparatus which do not incorporate such longitudinal  
35 elasticity, adjustability, telescoping, distensible or accordion configuration, the connector apparatus may be provided in a variety of different lengths and the

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operator may select the appropriate length of the connector apparatus prior to installation.

Still further in accordance with the invention, the leading edge of the apparatus may be a sharpened cutting edge or may be otherwise adapted to cut or sever tissue, such that the delivery and advancement of the apparatus through the openings in the anatomical structures and/or the passageway created therebetween may further serve to form such openings or passageway, or to enlarge, customize, model or otherwise alter the tissue with which it comes in contact.

Still further in accordance with the invention, there are provided connector apparatus having a connecting portion which comprises legs or members which penetrate through tissue surrounding the openings formed in the anatomical structures and/or any intervening tissue located therebetween, such that the connecting portion of the apparatus is embedded within the host tissue and is actually located outside of the channel or passageway formed between the first and second openings in the first and second anatomical structures.

Still further in accordance with invention, there are provided delivery systems and devices for delivering and implanting the connector apparatus of the present invention. These delivery apparatus and devices are typically incorporated into or mounted upon a transluminally advanceable catheter, and comprise a retractable sheath, inflatable balloon, push rod, alter-apposing slider sheaths, or rotatable members which operate to radially expand or advance the connector apparatus into its desired implantation position within the body.

These and other elements and objects of the present invention will be more fully understood and appreciated upon reading of the detailed description of preferred embodiments set forth herebelow, and studying

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of the accompanying drawings wherein the preferred embodiments are shown.

**Brief Description of the Drawings**

5        Figure 1 is a partial longitudinal sectional view of two adjacently positioned blood vessels having a blood flow passageway formed therebetween, and a connector apparatus of the present invention implanted within such blood flow passageway to facilitate and  
10       maintain the desired side-to-side connection between the blood vessels.

      Figure 2 is a perspective view of a coil-type connector apparatus of the present invention.

15       Figure 2' is a perspective view of a modified coil-type connector apparatus of the present invention.

      Figure 2'' is a perspective view of another modified coil-type connector apparatus of the present invention having a tubular mid portion.

20       Figure 2''' is a perspective view of another coil-type connector apparatus of the present invention having a fused mid-portion.

      Figure 2'''' is a side elevational view of a helical coil connector apparatus of the present invention which is biased to a longitudinally collapsed  
25       configuration.

      Figure 3 is a perspective view of a mesh type connector apparatus of the present invention.

30       Figure 3' is a perspective view of a mesh type connector apparatus of the present invention having optional engagement members formed on either end thereof.

      Figure 3'' is a perspective view of the mesh type connector apparatus of Figure 3' wherein the engagement members are self-splaying.

35       Figure 3''' is a perspective view of the mesh type connector apparatus of Figure 3' wherein the engagement members are pressure-splayable, and wherein the

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apparatus is shown in conjunction with a pressure-exerting balloon catheter which is useable to splay the engagement members at the desired implantation site.

5 Figure 4 is a perspective view of a tube type connector apparatus of the present invention.

Figure 4' is a perspective view of a tube type connector apparatus of the present invention having optional engagement members formed on either end thereof.

10 Figure 4'' is a perspective view of the tube type connector apparatus shown in Figure 4', wherein the engagement members are self-splaying.

Figure 4''' is a perspective view of the tube type connector apparatus shown in Figure 4', wherein the engagement members are pressure-splayable, and wherein the apparatus is shown in conjunction with a pressure-exerting balloon catheter which is useable to cause splaying of the engagement members at the desired implantation site.

20 Figure 5 is a perspective view of a cylindrical connector apparatus of the present invention comprising a solid (non-perforated) tube member having optional engagement members formed on either end thereof.

25 Figure 5' is a perspective view of a non-hyperbolic, cylindrical connector apparatus wherein the engagement members are self-splaying.

30 Figure 5'' is a perspective view of a cylindrical connector apparatus wherein engagement members are pressure-splayable, and wherein the apparatus is shown in conjunction with a pressure-exerting balloon-catheter which is usable to cause splaying of the engagement members at the desired implantation site.

35 Figure 5''' is a perspective view of a cylindrical connector apparatus wherein the tube member is formed of wire mesh having a multiplicity of openings or perforations formed therein, and multiple engagement members are formed on both ends of the tube member;

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Figure 5'''' is a perspective view of a cylindrical connector apparatus wherein the tube member is formed of wire mesh having a multiplicity of openings or perforations formed therein, and two (2) engagement members are formed on each end of the tube member, said engagement members being in direct alignment with one another;

Figure 5''''' is a perspective view of a cylindrical connector apparatus wherein the tube member is formed of a solid tube, and wherein engagement members comprising semi-circular wire projections are mounted on either end of the tube member;

Figure 6 is a perspective view of a two-piece rivet-type connector apparatus of the present invention having a first rib-in-groove connection system formed thereon.

Figure 6' is a perspective view of an alternative two-piece rivet-type connector apparatus of the present invention having a tapered friction-fit engagement system formed thereon.

Figure 6'' is a perspective view of another alternative two-piece rivet-type connector apparatus of the present invention having a second rib-in-groove or magnetic type engagement system formed thereon.

Figure 7a is a top plan view of a first elastomeric connector apparatus of the present invention comprising a tubular mid-portion having elastomeric engagement members formed at either end thereof.

Figure 7a' is a perspective view of the elastomeric connector apparatus of Figure 7a.

Figure 7b is a top plan view of another elastomeric connector apparatus of the present invention comprising a tubular mid portion having a non-circular lumen and engagement flanges formed at either end thereof.

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Figure 7b' is a perspective view of the connector apparatus shown in Figure 7b.

Figure 7c is a perspective view of a connector apparatus of the present invention comprising an elastomeric body having wire support members formed therein.

Figure 7d is a perspective view of a wire connector apparatus of the present invention.

Figure 7d' is a perspective view of the wire connector apparatus of Figure 7d having a cylindrical elastomeric or fabric sleeve formed thereon.

Figure 7d'' is a perspective view of another wire connector apparatus formed of two of the connector apparatus of Figure 7d, coupled together to form a singular apparatus.

Figure 8 is a perspective view of a sinusoidal wire connector apparatus of the present invention in a flattened configuration, prior to fabrication into its desired final configuration.

Figure 8a is a perspective view of the sinusoidal wire connector apparatus of Figure 8 following fabrication of into its desired final configuration, and showing the apparatus in a preferred implantation position forming a connection between adjacent tubular anatomical conduits.

Figure 9 is a perspective view of a triplet coil type connector apparatus of the present invention, showing the apparatus in a preferred implantation position forming a connection between adjacent tubular anatomical conduits.

Figure 10 is a longitudinal sectional view of a flanged tube connector of the present invention in a preferred implantation position forming a connection between adjacent tubular anatomical conduits.

Figure 10a is a perspective view of a segment of tubing which has been precut for fabrication into the flanged tubular connector apparatus of Figure 10.

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Figure 10b is a side elevational view of the pre-notched segment of tubing shown in Figure 10a.

Figure 11a is a perspective view of a first embodiment of a flanged roll-up connector apparatus of the present invention.

Figure 11b is a perspective view of a second embodiment of a flanged roll-up connector apparatus of the present invention.

Figure 11c is a perspective view of a flanged cylindrical connector apparatus of the present invention.

Figure 12 is a perspective view showing the manner in which any of the connector apparatus of the present invention may be modified to form a non-perpendicular connection between adjacent anatomical structures.

Figure 13 is a perspective view of a segment of myocardium showing an alternative application of the connector apparatus of the present invention to form a connection between a coronary blood vessel and a chamber of the heart.

Figure 14a is a schematic showing of a retractable sheath type delivery catheter useable to deliver connector apparatus of the present invention.

Figure 14b is a schematic showing of an inflatable balloon type delivery catheter useable to deliver connector apparatus of the present invention.

Figure 14c is a schematic showing of a push rod type delivery catheter useable to deliver connector apparatus of the present invention.

Figure 14d is a schematic showing of an alternating slider sheath type delivery catheter useable to deliver connector apparatus of the present invention.

Figure 14e is a schematic showing of a rotatable delivery catheter useable to deliver and implant connector apparatus of the present invention.

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Figure 15a is a showing of a two-piece connector apparatus as described and claimed in parent application Serial No. 08/730,327, modified to illustrate the manner in which the connecting portion of the connector apparatus may protrude through tissue and lay outside of the passageway which has been formed between the adjacent anatomical structures.

Figure 15a' is an exploded view of the connector apparatus shown in Figure 15a.

#### Detailed Description of the Preferred Embodiments

The following detailed description and the drawings to which it refers are provided for the purpose of describing and illustrating presently preferred embodiments of the invention, and are not intended to limit the scope of the claims in any way.

It is to be understood that each of the structural elements attributes and components shown in the drawings for an embodiment may be incorporated into or combined with any or all of the other embodiments of the invention, so long as such negation may be accomplished without negating the utility or functionality of that embodiment.

Furthermore, it is to be appreciated that no effort has been made to exhaustively describe and illustrate each and every possible embodiment of the invention having each and every possible design or structure feature combineable therewith.

Specifically, the following elements, adaptations or structural attributes may be incorporated into any or all of the embodiments described herein, irrespective of whether such elements, adaptations or attributes are specifically shown in any of the drawings.

1. Radio-opaque construction or radio-opaque markings to enable the connector to be

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visualized by fluoroscopy, x-ray or  
Roentgenographic techniques;

2. Non-obstructive or minimally obstructive  
to flow of fluid through the openings in the  
anatomical structures between which the  
connection is formed;

3. Non-thrombogenic or antithrombogenic  
when used in blood-contacting applications  
and/or anti-infective or anti-microbial  
and/or radioactive so as to deter neointimal  
growth or natural closure or narrowing of the  
passageway.

4. Capable of withstanding the range of  
pressures which will be encountered in the  
intended anatomical application, such as  
pressures 140-180mmhg in applications wherein  
connections between arteries or an artery and  
vein are formed;

5. Capable of being operatively installed  
without causing significant necrosis or  
enhancing or inducing proliferation of tissue  
surrounding the connector apparatus;

6. Capable of expanding/contracting or  
otherwise adapting to compliance changes  
between the connected anatomical structures;

7. The portions of the connector apparatus  
which abut against or engage the luminal or  
inner wall of each anatomical structure may  
be shaped to conform to that luminal or inner  
wall (e.g., engagement members or flanges may  
be hemi-cylindrical bowed or cupped to  
conform to the wall of a blood vessel to  
which connection is made);

8. The connector apparatus may be  
structured or designed to maintain a desired  
cross-sectional dimension or diameter of the  
openings formed in the adjacent anatomical

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structures and any interstitial passageway formed between such openings; and

9. The connector apparatus may preferably be formed of a continuous or single structural element having minimal likelihood of breakage or dismemberment after implantation.

10. Capable of incorporating a flow control element or valve (e.g., a one-way check valve) to control or maintain a specific pattern or type of flow (e.g., unidirectional flow) through the passageway.

11. The connection portion of the connector apparatus may be adapted to form passageways of various shapes (eg., cylindrical, ovoid, arcuate).

12. Capable of being removed after implantation.

13. The connector apparatus may be constructed with varying amounts of structural support or scaffolding, or may incorporate intraluminally placed structural or non-structural elements which will retard or restrain neointimal growth or natural closure or narrowing of the passageway.

14. The connector apparatus will preferably be capable of withstanding all forces (e.g., hemodynamic pressures, muscular contractions or other forces created by movement or impact of the body) which will be encountered following implantation, without resultant adverse effect (e.g., breakage, dislodgement, slippage, movement or other untoward affect on the connector apparatus).

15. The connector apparatus may be constructed and configured so as to apply residual forces to compress or otherwise

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minimize the length of the passageway between the first and second anatomical structures following implantation.

5 16. The connector apparatus may be adapted to receive and transmit energy supplied through the delivery apparatus (e.g., delivery catheter). Such energy may serve to modify the surrounding tissue which defines the openings in the first and second  
10 anatomical structures as well as any passageway created between interstitial tissue which resides between the anatomical structures.

15 17. The connector apparatus may be configured to control or define the geometric shape of the passageway so as to maximize flow performance and/or to minimize adverse flow conditions such as turbulence.

20 18. The connector apparatus may be constructed to support rotational twisting and torsion without adverse effects.

With reference to the drawings, Figure 1 provides a general showing of the manner in which the connector apparatus 10 of the present invention is implanted or  
25 installed within openings formed in adjacent blood vessels  $BV_1$ ,  $BV_2$  to maintain side-by-side connection and direct alignment of the side wall openings formed in the blood vessel  $BV_1$ ,  $BV_2$ . The blood vessels  $BV_1$ ,  $BV_2$  may be endogenous arteries and/or veins in their  
30 natural anatomical positions, or may constitute one endogenous artery or vein having a synthetic or biological tube graft placed in juxtaposition thereto.

i. Coil Connectors

35 Figures 2-2''' show several variations of a first embodiment 10a of the connector apparatus of the present invention. Each of the variants shown in Figures 2-2''' comprise a helical coil formed of

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resilient or superelastic wire 12, such coil having opposite ends of a first diameter  $D_1$  and a mid-portion of a second diameter  $D_2$ . The second diameter  $D_2$  of the mid-portion of the coil is smaller than the first diameter  $D_1$  of the ends, such that the apparatus 10a is generally of all hyperbolic or "hourglass" shape. However, it will be appreciated that other embodiments may also be provided, rather than the hyperbolic or hourglass shape shown in the drawings, the coil is of a cylindrical or frusto-conical shape and is provided with additional engagement members which extend laterally outward from the opposite ends of the coil. The wire 12 of which the apparatus, 10a is formed is sufficiently resilient or superelastic in the range of temperatures in which the apparatus 10a is used (i.e., at room temperature and body temperature) to allow the apparatus 10a to be initially radially compressed (and concurrently longitudinally elongated) into a relatively small diameter, compact configuration which may be inserted into the lumen of a delivery catheter. The delivery catheter is then advanced through the desired anatomical passageway (e.g., blood vessel  $BV_1$  or  $BV_2$  such that an opening of the catheter is located within the region between the side wall openings in the adjacent anatomical conduits or blood vessels  $BV_1$ , or  $BV_2$ . Thereafter, the apparatus 10a is expelled out of the catheter and permitted to resiliently or elastically reassume its hyperbolic or hourglass configuration, such that the ends of the first diameter  $D_1$  will engage the walls of each anatomical conduit or blood vessels  $BV_1$ ,  $BV_2$  and the mid-portion diameter  $D_2$  will reside within the space or tissue tunnel created between the side wall of openings in the adjacent anatomical conduits or blood vessels  $BV_1$ ,  $BV_2$ .

In the connector apparatus 10a shown in Figure 2, the entire apparatus 10a is formed of a tightly wound helical wire coil such that each adjacent convolution

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of the wire 12 is in close juxtaposition or abutment to the adjacent convolution thereof. This provides a hyperbolic coil of substantially continuous construction, as shown in Figure 2.

5        Figure 2' shows a variant of the first embodiment of the connector apparatus 10a wherein the resilient or superelastic wire 12 is tightly wound at either end such that multiple adjacent convolutions of the wire are closely spaced or in direct abutment at either end  
10      of the apparatus 10a', while the mid-portion of the apparatus D<sub>2</sub> comprises a more loosely wound traversing segment 14 comprising a single strand of the wire 12 which extends from the abutting convolutions at one end of the apparatus 10a' to the abutting convolutions at  
15      the other end of the apparatus 10a'.

      In the variant shown in Figure 2'', the apparatus 10a'' comprises tightly wound helical wire coil segments of generally spiral or frusto-conical configuration located at either end, with a tubular  
20      sleeve 16 forming the mid portion of the apparatus 10a''. This tubular sleeve 16 may be formed of tubular plastic material such as polytetrafluoroethylene (PTFE), expanded polytetrafluoroethylene (EPTFE)  
polyethylene (PE), silicone, polyurethane (PU), or  
25      polyester. Alternatively, the tubular sleeve 16 may be formed of natural, autologous or xenograft material. The spiral or frusto-conical wire coil segments located at either end of the apparatus 10a'' may comprise the opposite ends of a continuous wire coil which extends  
30      through the lumen of the tubular sleeve 16, or may comprise two separate, non-continuous coil segments each of which is affixed or mounted to one end of the tubular sleeve 16.

      The variant of the connector apparatus 10a'''  
35      shown in Figure 2''' comprises a continuous, tightly wound helical coil of resilient or superelastic wire 12 which is similar in configuration to that shown in

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Figure 2, but wherein two or more adjacent convolutions of the wire 12 at the mid-portion of the apparatus 10a''' have been welded, adhered or otherwise fused to one another to form a continuous, tubular mid-portion of diameter  $D_2$ . Such fusion of the adjacent convolutions of wire 12 forming the mid-portion of the apparatus 10a''' may comprise weldments 18, or adhesive or any other suitable fusion material capable of welding adhering or otherwise fusing the adjacent convolutions of wire 12 to one another.

It will be appreciated that many of the embodiments of the connector apparatus 10 of the present invention may be constructed so as to be biased to a longitudinally shortened or longitudinally collapsed configuration so as to longitudinally compress or confine the tissue between the first and second openings formed in the first and second anatomical structures or blood vessels  $BV_1$ ,  $BV_2$ . Figure 2'''' shows an example of this concept, as applied to the helical coil connector of Figure 2. As shown in Figure 2''''', the helical coil connector 10a''''', when in its relaxed state, has a longitudinally compact configuration wherein the first and second ends of the coil are close-spaced. When this embodiment of the connector apparatus 10a'''' is implanted within the first and second openings formed in the first and second anatomical structures or blood vessels  $BV_1$ ,  $BV_2$ , the opposite ends of the connector apparatus 10a'''' will engage the openings in the adjacent anatomical structures or blood vessels  $BV_1$ ,  $BV_2$  and will conform to the length of the channel formed therebetween. In this manner, the resilient nature of the coil will tend to urge or pull the opposite ends of the coil inwardly, thereby longitudinally compressing or constraining the tissues which are located between the opposite ends of the coil. It should be noted, however, that the force exerted by the coil is preferably not too great as to

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cause undesirable tissue necrosis or undesirable proliferation of tissues which are longitudinally compressed or constrained by this embodiment of the apparatus 10a'''''. It will be further appreciated that the biasing of the connector apparatus 10a''''' to such longitudinally compact configuration will enable the connector apparatus 10a''''' to be used in channels or passageways of varying length, thereby eliminating the need for providing manufacturing and stocking a variety of such connector apparatus 10a''''' having differing lengths.

ii. Mesh Connectors

Figures 3-3''' show several variants of tubular mesh connector apparatus 10b having inwardly arched (e.g., hyperboloidal side walls.)

Figure 3 shows a basic hyperbolic mesh connector apparatus 10b which comprises a tube formed of wire mesh having an inwardly arched, hyperboloidal or "hourglass" configuration. However, it will be appreciated that the wire mesh connectors may alternatively be of cylindrical or frusto-conical configuration with additional engagement members or projections extending laterally outward from the opposite ends of such cylindrical or frusto-conical mesh tube. This embodiment of the connector apparatus 10b has distal ends of a first diameter  $D_1$  and a second diameter  $D_2$ . The diameter  $D_2$  of the mid-portion is smaller than the diameters  $D_1$  of the ends, thereby providing the desired hyperbolic or hourglass configuration. The mesh structure of the apparatus 10b is preferably formed of a multiplicity of wire segments 18 which are interwoven into the desired mesh structure. The wire segments 18 may be formed of a resilient or superelastic wire material so as to render the apparatus 10b radially compressible (and concurably longitudinally elongatable) to a reduced diameter capable of being positioned within a delivery catheter,

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and to subsequently allow the apparatus 10b to resiliently self-expand to its desired hyperbolic or hourglass configuration of diameters  $D_1$  and  $D_2$  after having been expelled from the constraining catheter or other delivery device. In some applications, the hyperbolic or hourglass configuration of the apparatus 10b will be such that the end portions of diameter  $D_1$  will engage the walls of the adjacent anatomical passageways or blood vessels  $BV_1$ ,  $BV_2$ , so as to hold the apparatus 10b in the desired position between the anatomical passageways or blood vessels  $BV_1$ ,  $BV_2$ . In other embodiments, as show in Figures 3', 3'', and 3''', one or more splayable engagement members 20 may be formed on one or both ends of the wire mesh tube to facilitate engagement of the opposite ends of the apparatus 10b to the walls of the connected anatomical passageways or blood vessels  $BV_1$ ,  $BV_2$ .

Figure 3' shows a variant of the apparatus 10b' having wire loop type engagement members 20 formed on both ends thereof. Initially, as shown in Figure 3', the wire loop type engagement members 20 will be deployed in extended positions such that they extend longitudinally from either end of the wire mesh tube and are parallel or close to parallel to the longitudinal axis LA of the apparatus 10b'. These engagement members 20 may be formed of resilient or spring material so as to be self splaying (Fig. 3'') or may be formed of bendable or malleable material so as to be pressure-splayable (Fig. 3''').

With reference to the particular variant Figure 3'', the resilient or self-splayable engagement members 20 will, when released from the surrounding constraint of the delivery catheter, self-splay (i.e., curve outwardly) to their desired engagement positions wherein such engagement members 20 may be generally perpendicular or near perpendicular to the longitudinal axis LA of the device 10b''.

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With reference to Figure 3''', in embodiments wherein the engagement members 20 are formed of plastically deformable or malleable metal or other material which is pressure-deformable, the apparatus 10b''' will be initially positioned within the adjacent openings formed in the first and second anatomical passageways or blood vessels  $BV_1$ ,  $BV_2$  such that the engagement members 20 formed on one end of the apparatus 10b''' protrude or extend into the lumen of the first anatomical passageway or blood vessel  $BV_1$  and the engagement members 20 on the opposite end of the apparatus 10b''' protrude or extend into the lumen of the second anatomical passageway or blood vessel  $BV_2$ . A pressure exerting apparatus, such as the dual balloon catheter 24 shown in Figure 3''', is then utilized to exert, pressure against the engagement members 20 to cause the engagement members to splay or deform outwardly to positions which are substantially perpendicular or near perpendicular to the longitudinal axis LA of the apparatus 10b'', or such that the engagement members will embed or hook into the adjacent tissue of the anatomical structure. In this manner, the engagement members 20 may abut against or enter the adjacent walls of the first and second passageways or blood vessels  $BV_1$ , or  $BV_2$ . One type of dual balloon catheter 24 useable for this purpose comprises an elongate pliable catheter 26 having a singular dumbbell-shaped or hour glass shaped balloon or the combination of a first balloon 28 and a second balloon 30 formed at spaced apart location thereon, as shown. The first balloon 28 and second balloon 30 are spaced apart or separated by a distance which is equal to, or bears a predetermined relationship to, the length of the apparatus 10b''' such that the first balloon 28 may be positioned within and adjacent the longitudinally extended engagement members 20 on one end of the apparatus 10b''' and the second balloon 30 may be

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positioned within and adjacent the longitudinally extended engagement members 20 on the other end of the apparatus 10b'''. Thereafter, the first and second balloons 28, 30 are inflated causing them to exert pressure against the engagement members 20 on both ends of the apparatus 10b''', resulting in the desired splaying or bending of the engagement members 20 to their engagement positions wherein they are generally in apposition to, or embedded in, the wall(s) of the anatomical structure on either side of the channel. Thereafter, the first balloon 28 and second balloon 30 are deflated and the catheter 26 is removed, leaving the connector apparatus 10b''' in its installed and implanted location between the first and second passageways or blood vessels  $BV_1$ ,  $BV_2$ .

### iii. Tube Connectors

Figure 4-4''' show several variants of a tube connector apparatus 10c 10c''' which generally comprises a segment of radially compressible or collapsible resilient tube member 30 having inwardly arched, hyperboloidal or "hourglass" shaped side walls having opposite ends of a first diameter  $D_1$  and a mid-portion of a second diameter  $D_2$ . It will be appreciated, however, that the tube may alternatively be of cylindrical or frusto-conical shape with additional engagement members which extend laterally outward from either end of the tube, which may not require expansion for placement.

Specifically, Figure 4 shows a connector apparatus 10c which comprises a hyperbolic or hourglass shaped tube member 36 which is positionable within side openings formed in two adjacent anatomical passageways (e.g., blood vessels  $BV_1$ ,  $BV_2$ ) such that one end of the tube member 36 having diameter  $D_1$  will engage the luminal surface of the one of passageways or blood vessels  $BV_1$  and the other end of the tube member 36 also of diameter  $D_1$  will engage the luminal surface of

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the other passageway or blood vessel  $BV_2$ . The outwardly tapered or enlarged diameters of the ends of the tube members 36 thus serve to engage the anatomical passageways or blood vessels  $BV_1$ ,  $BV_2$  without the need  
5 for additional flanges, projections or other engagement members on either end of the tube member 36.

Figure 4' shows the hyperbolic tube member 36 of Figure 4 with optional engagement members 20 formed on both ends thereof. These engagement members 20 may  
10 comprise flanges, tabs, or, as shown, splayable wire loops. These engagement members 20 are initially disposed such that they extend longitudinally from either end of the hyperbolic tube member 36 and are parallel or close to parallel to the longitudinal axis  
15 LA of the tube member 36. After the tube member 36 has been placed in its desired position between the two anatomical passageways or blood vessels  $BV_1$ ,  $BV_2$ , the engagement members 20 are caused to splay outwardly such that they become perpendicular or close to  
20 perpendicular to the longitudinal axis LA of the tube member 36, as shown in Figures 4'' and 4'''. The engagement members 20 may be formed of resilient, superelastic, shape memory or spring material so as to be self-splayable (Fig. 4'') or may be formed of  
25 bendable or plastically deformable material so as to be pressure-splayable (Fig. 4''').

With reference to Figure 4'', a self-splayable embodiment of the apparatus 10c comprises engagement  
30 members 20 which, when relieved of the surrounding constraint of a delivery catheter or other delivery apparatus, will self-splay to their outwardly deployed positions wherein they are generally perpendicular or close to perpendicular to the longitudinal axis LA of the apparatus 10c''.

35 With reference to Figure 4''', there is shown an embodiment of the apparatus 10c''' wherein the engagement members 20 are pressure-splayable. This

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embodiment of the apparatus 10c''' is initially positioned such that the engagement members 20 on one end of the apparatus 10c''' extend into the lumen of one anatomical passageway or blood vessel  $BV_1$ , and the engagement members 20 on the other end of the apparatus 10c''' extend into the lumen of the second anatomical passageway or blood vessel  $BV_2$ . A pressure exerting apparatus, such as the above-described balloon catheter 26 having first and second balloons 28, 30, is then utilized to exert pressure upon the engagement members 20 to cause the engagement members to move from their longitudinally extended positions (Fig. 4') to their outwardly splayed (i.e., operative positions wherein they are generally perpendicular or close to perpendicular to the longitudinal axis LA of the apparatus 10c'''. Thereafter, the balloons 28, 30 of the balloon catheter 26 or other pressure-exerting elements of any suitable pressure-exerting tool are deflated or otherwise disengaged and the catheter 26 is removed, thereby leaving the apparatus 10c in its desired position between the first and second anatomical passageways or blood vessels  $BV_1$ ,  $BV_2$ , with the engagement members 20 in direct abutment with the lumen surfaces of the respective first and second passageways or blood vessels  $BV_1$ ,  $BV_2$ .

iv. Cylindrical Connectors with Engagement Surface

Figures 5-5'' show several variants of a cylindrical connector apparatus 10b of the present invention. This cylindrical connector apparatus 10b generally comprises a cylindrical, tubular mid-portion 38 of substantially constant diameter, in combination with one or more engagement members 20 formed on either end thereof. The engagement members 20 may comprise splayable wire loops as shown in the drawings, or any other suitable type of flange, lip, tab or other member capable of abutting against the luminal wall of an

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anatomical passageway or blood vessel  $BV_1$ ,  $BV_2$  to prevent longitudinal slippage or movement of the tubular mid-portion in at least one direction. In this manner, the formation and deployment of such engagement member on either end of the tubular mid-portion 38 will anchor and hold the tubular mid-portion 38 in its desired implantation position between the openings formed in the adjacent passageways of blood vessels  $BV_1$  and  $BV_2$ .

10 The tubular mid-portion 38 of the apparatus 10d may comprise a tube of resilient plastic, woven dacron or any other suitable material which is collapsible to a small diameter so as to be initially packed within the lumen of a delivery catheter, and which is  
15 subsequently radially expandable or unfoldable to a desired diameter D such that blood or other bodily fluid may flow through the cylindrical tubular member 38 from one anatomical passageway or blood vessel  $BV_1$  into another anatomical passageway or blood vessel  $BV_2$ .  
20 Alternatively, it will be appreciated that the tubular mid-portion 38 may be a rigid or semi-rigid tube formed of metal, carbon or alloy which is generally not radially expandable, but which is provided with additional engagement members which may be splayed or  
25 extended from opposite ends of the tubular mid-portion 38 to engage or embed within the adjacent tissue of the anatomical structure. These rigid or semi-rigid tubular mid-portions 38 may be of any suitable shaped configuration, including cylindrical, frusto-conical or  
30 hyperbolic (e.g., hourglass) shape.

The engagement members 20 are preferably initially disposed in positions wherein they are longitudinally extended from either end of the cylindrical tubular mid-portion 38 generally parallel or close to parallel  
35 to the longitudinal axis LA of the apparatus 10d as shown in Figure 5. The engagement members 20 may be formed of resilient, superelastic, shape memory or

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spring material so as to be self-splayable (Fig. 5) or may be formed of bendable or plastically deformable material so as to be pressure-splayable (Fig. 5'')

With reference to Figure 5', a self-splayable embodiment of apparatus 10d comprises engagement members 20 which, when relieved of the surrounding constraint of the delivery catheter or other delivery apparatus, will self-splay to their outwardly deployed position wherein they are generally perpendicular or close to perpendicular to the longitudinal axis LA of the apparatus 10b'.

With reference to Figure 5'', in embodiments of the apparatus 10b'' wherein the engagement members 20 are pressure-splayable. This embodiment of the apparatus 10b'' is initially positioned such that the engagement members 20 on one end of the apparatus 10b'' extend into the lumen of one anatomical passageway or blood vessel  $BV_1$  and the engagement members 20 on the other end of the apparatus 10b'' extend into the lumen of the second anatomical passageway or blood vessel  $BV_2$ . A pressure exerting apparatus, such as the above-described balloon catheter 26 having first and second balloons 28, 30, is then utilized to exert pressure upon the engagement members 20 to cause the engagement members to move from their longitudinally extended positions (Fig. 5) to their outwardly splayed (i.e., operative) positions wherein they are generally perpendicular or close to perpendicular to the longitudinal axis LA of the apparatus 10d'' (Fig. 5''). Thereafter, the balloons 28, 30 of the balloon catheter 26 or other pressure-exerting elements of any suitable pressure-exerting tool are deflated or otherwise disengaged and the catheter 26 is removed, thereby leaving the apparatus 10d'' in its desired position between the first and second anatomical passageways or blood vessels  $BV_1$ ,  $BV_2$  with the engagement members 20

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in direct abutment with the respective first and second passageways or blood vessels  $BV_1$ ,  $BV_2$ .

v. Rivet Type Connector Apparatus

Figure 6-6'' show several variants of rivet type connector apparatus which comprise a first tubular member 40 having a first engagement flange 44 formed thereon and a second tubular member 42 having a second engagement flange 46 formed thereon. The first and second tubular members 40, 42 are connectible to one another such the lumens of the tubular members 40, 42 are in direct alignment thereby forming a singular lumen 41 through the center of the apparatus 10e, 10e', 10e''.

Various snap-fitting or frictional engagement systems may be utilized to securely connect the first and second tubular members 40, 42 to one another, and examples of such snap-fitting or frictional engagement systems are shown in the showings of Figures 6, 6' and 6''.

With specific reference to Figure 6, there is provided an annular groove 48 in the outer surface of the first tubular member 40 and a corresponding raised ridge 50 in the outer surface of the second tubular member 42. The raised ridge 50 is sized and configured to snap fit and seat within the groove 48 as the first tubular member 40 is advanced into the interior of the second tubular member 42. When the annular ridge 50 is seated within the corresponding groove 48, the respective engagement flanges 44, 46 will be held in fixed spaced-apart relation to one another such that the distance between flanges 44, 46 will result in engagement of the flanges with the respective luminal walls of the anatomical passageways or blood vessels  $BV_1$ ,  $BV_2$  which are intended to be connected by the apparatus 10e.

Figure 6' shows another connector apparatus 10e comprising a first tubular member 40' and a second

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tubular member 42'. Engagement flanges 44', 46' are formed about the outer ends of the first and second tubular members 40', 42', respectively. When the non-flanged end of the first tubular member 40' is advanced into the non-flanged end of the second tubular member 42', the respective lumens of the two tubular members 40', 42' will be in direct alignment so as to form a single continuous lumen 41 through the center of the apparatus 10e'. The outer surface of the first tubular member 40 is tapered inwardly toward the non-flanged end such that, as it is advanced into the interior of the second tubular member 42' the outer surface of the first tubular member 40' will tighten against and frictionally engage the inner surface of the second tubular member 42', thereby holding the first and second tubular members 40', 42' in fixed, connected relation to one another such that the engagement flanges, 44', 46' are held in spaced-apart relation such that the distance therebetween will cause the flanges 44', 46' to be in abutting contact with the respective luminal surfaces of the first and second passageways or blood vessels BV<sub>1</sub>, BV<sub>2</sub>.

vi. Elastomeric Connector Apparatus

Figures 7a-7d' show examples of connector apparatus 10h, 10i of the present invention formed of elastomeric materials such as a resilient elastomeric polymer (e.g., polyurethane, silicone, etc.).

In particular, Figures 7a, 7a' show an embodiment of a connector apparatus 10h comprising an elastomeric, cylindrical tube 60 having a hollow lumen 62 extending longitudinally therethrough and four engagement members in the nature of tabs formed on opposite ends of the tube 60 and extending outwardly therefrom in directions which are substantially perpendicular to the longitudinal axis LA of the tube 60.

Figures 7b, 7b' show another embodiment of a connector apparatus 10i which comprises an ovoid tube

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member 70 formed of elastomeric material and substantially rectangular engagement members 74 in the nature of flanges formed on either end thereof. The engagement members 74 extend in directions which are parallel to the length-wise axis of the ovoid lumen 72 of the ovoid tube member 70, as shown. The provision of the ovoid tube member 70 having the ovoid lumen 72, and the corresponding configuration and directional orientation of the engagement members 74 will enable this embodiment of the connector apparatus 10i to be utilized in blood vessels or anatomical passageways of relatively small diameter, with openings which are elongate or ovoid so as to permit a greater amount of body fluid to flow through the openings than would be possible than if the openings were of a circular configuration. This is due to the fact that the maximum diameter of any circular opening formed in the side wall of a passageway or blood vessel  $BV_1$ ,  $BV_2$  cannot exceed the diameter of the passageway or blood vessel  $BV_1$ ,  $BV_2$ , while elongate or ovoid openings may have a width which is equal to or slightly less than the diameter of the passageway or blood vessel  $BV_1$ ,  $BV_2$  and a length which is larger than the diameter of such passageway or blood vessel  $BV_1$ ,  $BV_2$ . This tube member 70 may also incorporate any suitable reinforcing material, such as wire. This ovoid or non-circular configuration of the tube member 70 and its lumen 72 may be incorporated into any of the embodiments of the invention described herein, and is not necessarily limited to the particular elastomeric embodiment shown in Figures 7b, 7b'.

In each of these elastomeric embodiments shown in Figures 7a, 7a', 7b, 7b', the material of which the apparatus 10h, 10i is formed is sufficiently resilient and compressible to be initially packed into the lumen of a delivery catheter, and is sufficiently resilient such that when the apparatus 10h, 10i is expelled or

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otherwise passed out of the delivery catheter, the absence of restraint upon the apparatus 10h, 10i will allow the apparatus to assume its fully expanded and operative configuration as shown in the figures. When  
5 in such fully expanded and operative configuration, the abutment members 64 or 74 will abut against the luminal surfaces of the passageways or blood vessels  $BV_1$ ,  $BV_2$ , in the regions immediately surrounding the openings formed therein, and the tube members 60, 70 of the  
10 apparatus 10h, 10i will extend between the respective passageways or blood vessels  $BV_1$ ,  $BV_2$ , thereby forming a conduit or passageway between the openings formed in the passageways or blood vessels  $BV_1$ ,  $BV_2$ .

15 **vii. Wire Connector Apparatus with Optional Covering**

Figure 7c-7d' show examples of wire connector members with optional coverings formed thereon. These coverings may cover all or any portion of the apparatus. For example, such covering may be formed on  
20 the connecting portion or mid-portion of the apparatus so as to form a sleeve or covering which lines the passageway, while the engagement portions (e.g., extendable engagement members) of the apparatus may remain devoid of such covering. Such coverings may be  
25 formed of any suitable material including, but not limited to, elastomeric material, fabrics (e.g., woven polyester) or natural materials such as autologous or xenograft material.

With specific reference to the embodiment shown in  
30 Figure 7c, there are provided two separate generally U-shaped wire members 80 which are partially embedded with an elastomeric tube member 82 having a hollow lumen 84 extending longitudinally therethrough. Optionally, the portions of the wire members 80 which  
35 protrude out of the elastomeric tube member 82 may also be covered with elastomeric material 86. In this manner, the portions of the wire members 80 (with or

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without elastomeric covering 86) which protrude outwardly from the elastomeric tube member 82 may serve to abut against and engage the luminal surfaces of the passageways or blood vessels  $BV_1$ ,  $BV_2$ , immediately adjacent the side wall openings formed therein, while the elastomeric tube member 82 will form a traversing conduit between the passageways or blood vessels  $BV_1$ ,  $BV_2$ . In this manner, the protruding portions of the wire members 80 with or without their elastomeric coverings 86 will serve to anchor and hold the apparatus 10j in its desired position between the passageways or blood vessels  $BV_1$ ,  $BV_2$ , such that body fluid may pass through the lumen 84 of the tube member 82, from one of the passageway or blood vessel  $BV_1$  to the other passageway or blood vessel  $BV_2$ .

Figure 7d-7d' shows another embodiment of a connector apparatus 10k which comprises a continuous segment of wire which is formed into a configuration having four generally U-shaped projections 92 extending laterally outward therefrom in opposite directions.

This apparatus 10k may be utilized as a connector apparatus in and of itself, without any elastomeric covering, such that the U-shaped projection 92 may be placed in abutment with the luminal surfaces of the adjacent passageways or blood vessels  $BV_1$ ,  $BV_2$ , thereby clipping or holding the openings formed in the passageways or blood vessels  $BV_1$ ,  $BV_2$  in alignment with one another, and establishing the desired interconnection of the passageways or blood vessels  $BV_1$ ,  $BV_2$ .

Figure 7d' shows an optional elastomeric tube member 94 having the central portion of the wire member formed therein such that the U-shaped projections 92 extend laterally outboard and away from the elastomeric tube member 94. In this manner, the elastomeric tube member is provided with a hollow lumen 96 extending longitudinally therefrom and, when the U-shaped

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projections 92 are in abutment with the luminal surfaces of the passageways or blood vessels  $BV_1$ ,  $BV_2$ , the elastomeric tube member 94 will form a discrete conduit or passageway whereby body fluid may pass through the lumen 96 of the tube member 94 from one passageway or blood vessel  $BV_1$  to the other passageway or blood vessel  $BV_2$ . Optionally, the elastomeric material may also extend over and cover the U-shaped projections 92, as denoted by the dotted lines in Figure 7b'.

viii. Sinusoidal Wire Connector Apparatus

Figures 8-8a show a connector apparatus 101 which is formed of a wire member 100 which has been formed or bent into multiple sinusoidal waves or convolutions, some of such sinusoidal waves or convolutions being of a first size 102 and others of such sinusoidal waves or convolutions being of a second size 104. Preferably the smaller sinusoidal waves or convolutions 102 are formed in pairs or couplets, with the larger sinusoidal waves or convolutions 104 being also formed in pairs or couplets which are positioned alternately with the pairs or couplets of the smaller sinusoidal waves or convolutions 102. In this manner, when the opposite ends of the wire member 100 are fused or coupled together by way of a sleeve member 101, the smaller sinusoidal waves or convolutions 102 will define a hollow passageway 106 and the larger sinusoidal waves or convolutions 104 may be bent laterally outward from the center of the passageway 106 so as to abut against and engage the respective luminal surfaces of the anatomical passageways or blood vessels  $BV_1$ ,  $BV_2$ , as shown in Figure 8a. In this manner, the sinusoidal wire connector apparatus 101 shown in Figures 8, 8a serves to hold the first and second blood vessels  $BV_1$ ,  $BV_2$  in connection with one another such that side wall openings formed in such first and second blood vessels  $BV_1$ ,  $BV_2$  will be maintained in direct alignment with

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one another, thereby allowing body fluid to pass through the passageway 106 of the connector apparatus 101 from the lumen of one blood vessel  $BV_1$  to the lumen of the other blood vessel  $BV_2$ .

5 It will be appreciated that a covering formed of any suitable material (e.g., elastomeric, fabric, natural graft material, etc.) may be formed on all or part of the device. for example, a tubular covering may be mounted on the mid-portion formed by the smaller  
10 sinusoidal waves or convolutions 102 and the basal portions of the larger sinusoidal waves or convolutions 104, and such cover may optionally may extend outwardly over the entireties of the laterally bent portions of the larger sinusoidal waves or convolutions 104, in  
15 accordance with the invention as described hereabove in relation to Figures 7c and 7d'.

**ix. Triplet Coil Type Connector Apparatus**

Figure 9 shows a triplet coil type connector apparatus 10m of the present invention comprising a  
20 first coil portion 114a, a second coil portion 114b and a third coil portion 114c. The apparatus 10m is formed of a continuous wire member 110 which has been helically wound to form a coil wherein adjacent convolutions of the coil are in direct abutment with  
25 one another, or are closely spaced to one another.

The first coil segment 114a has a first longitudinal axis  $LA_1$ . The coil segment 114b has a second longitudinal axis  $LA_2$  which may be perpendicular to the first longitudinal axis  $LA_1$  of the first coil  
30 segment 114a. The third coil segment 114c has a third longitudinal axis  $LA_3$  which may be parallel to the first longitudinal axis  $LA_1$  of the first coil segment 114a and perpendicular to the second longitudinal axis  $LA_2$  of the first coil segment 114b.

35 The length l of the second coil segment 114b may vary depending upon the desired distance between the first and second passageways or blood vessels  $BV_1$ ,  $BV_2$ .

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The wire member 110 may be formed of any suitable material such as stainless steel, superelastic nickel titanium alloy, etc. The apparatus 10m is preferably sufficiently pliable and resilient such that the three  
5 coil segments 114a, 114b, 114c may be disposed in direct alignment with one another about a common longitudinal axis and radially compressed (and concurrently elongated) so as to be positionable within the lumen of a delivery catheter. For most  
10 intravascular applications, it will be desirable to compress the entire apparatus 10m to a compact configuration which may be mounted within or upon a delivery catheter of the type referred to in more detail herebelow. Thereafter, the delivery catheter  
15 may be advanced through the second blood vessel  $BV_2$ , through the opening formed between the second blood vessel  $BV_2$  and first blood vessel  $BV_1$ , and into the lumen of the first blood vessel  $BV_1$ . Thereafter, the third coil segment 114c will be expelled out of the  
20 delivery catheter and allowed to assume its radially expanded, operative configuration as shown in Figure 9.

Thereafter, the delivery catheter will be retracted to a position within or adjacent the opening between the first blood vessel  $BV_1$  and second blood  
25 vessel  $BV_2$ , and the second coil segment 114b will be expelled or advanced out of the delivery catheter and allowed to radially expand to its expanded, operative configuration and attitude about the second longitudinal axis  $LA_2$  as shown in Figure 9.  
30 Thereafter, the delivery catheter is further retracted into the lumen of the second blood vessel  $BV_2$  and the first coil segment 114a is expelled or advanced out of the delivery catheter and allowed to expand to its expanded, operative configuration as shown in Figure 9.  
35 In this manner, the first and third coil segments 114a, 114c will seat against and frictionally engage the luminal surfaces of the first and second blood

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vessels  $BV_1$  and  $BV_2$ , respectively, and the second coil segment 114b will traverse any space which exists between the first and second blood vessels  $BV_1$  and  $BV_2$ . It will be appreciated, that a tubular covering or enclosure may be formed upon the inner and/or outer surfaces of any and/or all of the coil members 114a, 114b, 114c to provide a flow conduit which is impermeable to fluid, or to enhance the biocompatibility of the apparatus 10m.

10        **x. Flanged Tube Type Connector Apparatus**

Figures 10-10b show a flanged tube type connector apparatus 10n of the present invention. It will be appreciated that, in addition to the specific flang configurations shown in the drawings, such flanges may be formed in many different configurations and designs and/or may include notches, geometries and configurational attributes designed to enhance the ability of the connector apparatus to withstand longitudinal contractions/expansions and rotational/orientation motions of the surrounding tissue.

The embodiment 10n shown in Figure 10, comprises a segment of tubing which has been notched and formed such that semi-cylindrical or arcuate flanges 120 extend laterally outward from opposite sides of either end of a cylindrical or tubular mid-portion 122. When implanted between two blood vessels, as illustrated in Figure 10, the semi-cylindrical or arcuate flanges 120 will abut against the luminal surfaces of the blood vessels and will approximate the semi-cylindrical or arcuate shape of the adjacent luminal blood vessel surface. The tubular or cylindrical mid-portion 22 forms a discrete tubular conduit which extends between the openings formed in the adjacent blood vessels, thereby providing a substantially fluid tight conduit through which blood or other bodily fluid may pass.

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Figures 10-10b illustrate a preferred method of manufacturing this flanged tube type connector apparatus 10n. With reference to Figure 10a, a segment of cylindrical tubing formed of resilient metal, resilient plastic, shape memory alloy or other suitable material is precut such that two (2) longitudinal notches 124 (e.g., rectangular notches) are formed in each end of the tube, at locations directly opposite one another, as shown. Thereafter, two transverse notches 126 (e.g., arcuate or wedge shaped notches) are formed on either side of the tube such that the center of each such transverse notch 126 is approximately 90° from the centers of the adjacent longitudinal notches 124 formed on that end of the tube. Thereafter, the protruding end portions of the notched tube are deformed or bent outwardly, as indicated by the arrows on Figure 10a. This results in the formation of the connector apparatus 10n shown in Figure 10 comprising the tubular mid-portion 122 having the arcuate or semi-cylindrical flanges 120 which extend laterally outward from each end of the tubular mid-portion 122.

**xi. Cylindrical Connectors Having Ribbed Outer Surfaces**

Figures 11a-11c show three embodiments of externally ribbed cylindrical connectors 10o, 10p, 10q of the present invention.

The connector 10o shown in Figure 11a comprises a cylindrical or tubular body 130 formed of a rolled sheet of resilient metal or plastic having overlapping ends 132 such that the rolled cylindrical body may be radially compressed to a radially compact diameter, and will subsequently resiliently return to a radially expanded diameter as shown in Figure 11a. Cylindrical flanges or ribs 134 are formed about either end of the rolled tube 130, as shown. In this manner, the apparatus 10o may be held in its radially compact state within an introducer or catheter and delivered into a

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passageway formed between two anatomical structures, where it is allowed to radially expand to its operative configuration. Such radial expansion will cause the flange 134 at one end of the rolled cylindrical body 130 to abut against and engage the luminal surface of a first blood vessel or anatomical structure, surrounding a first opening formed in that blood vessel or anatomical structure. Similarly, the flange or rib 134b at the opposite end of the rolled tubular body 130 will abut against and engage the luminal surface surrounding an opening formed in a second blood vessel or other anatomical structure.

Figure 11b shows another ribbed connector apparatus 10p which also comprises a rolled cylindrical body portion 136 formed and configured the same as that shown in Figure 11a. In this apparatus 10p, a plurality of annular flanges or ribs 138 are formed about the outer surface of the rolled cylindrical body 136. When this apparatus 10p is delivered into a passageway between two blood vessels or other anatomical structures and allowed to expand, the flanges or ribs 138 on the outer surface of the rolled cylindrical body will embed into or engage interstitial tissue which surrounds the cylindrical body 136, thereby holding the apparatus 10p in its desired position between openings formed in adjacent blood vessels or anatomical structures. It will be appreciated that this embodiment of the apparatus 10p will be particularly useful in applications wherein firm interstitial tissue surrounds the passageway which extends between the openings formed in the adjacent blood vessels or anatomical structures. Indeed, this apparatus 10p is devoid of any flanges projections or surfaces which will abut against or engage the luminal surfaces of the adjacent blood vessels or anatomical structures, and relies instead on the engagement of the ribs or flanges 138 with the interstitial tissue to

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prevent the apparatus 10p from dislodging or longitudinally moving following implantation.

Figure 11c shows another example of a ribbed cylindrical connector apparatus 10g comprising a continuous cylindrical tubular body 140 having a helical rib or flange 142 formed about the outer surface thereof. The continuous cylindrical body 140 differs from the rolled cylindrical bodies of the embodiments 10o, 10p shown in Figures 11a and 11b in that it does not have overlapping ends and can not be radially compressed in a "roll-up" state. Rather, the cylindrical body 140 of this apparatus 10g is of a continuous cylindrical structure and is formed of resilient or collapsible material that will enable the apparatus 10g to be placed in a radially compact or reduced state for delivery into a passageway formed between openings and adjacent blood vessels or anatomical structures. After the tubular body 140 has been delivered and expanded to its operative configuration as shown in Figure 11c, the helical outer rib or flange 142 will engage the interstitial tissue surrounding the passageway. As in the embodiment shown in Figure 11b, this apparatus 10g will be particularly useable in applications wherein the passageway formed between the blood vessels or other anatomical structures has firm surrounding interstitial tissue into which the helical rib or flange 142 may imbed.

xii. Possible Modifications Of Embodiments To Accommodate Diagonal Passageways or Connections Between Anatomical Structures Other Than Blood Vessels

Figures 12 and 13 are intended to show modifications and alternative applications which may be applicable to all of the connector apparatus shown in Figures 1-11.

Figure 12 is illustrative of the concept of forming the ends of each connector apparatus 10 such

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that the ends are non-perpendicular to the longitudinal axis LA of the apparatus 10. Such angle-cutting of the ends of the connector apparatus 10 will be applicable when the connector apparatus 10 is to be disposed  
5 within a diagonal or curved passway formed between openings which are not directly opposite one another on adjacent anatomical structures or blood vessels BV<sub>1</sub>, BV<sub>2</sub>. This aspect of the invention will be particular applicable in certain arterial bypass procedures, such  
10 as those described in United States Patent Applications Serial Nos. 08/730,327 and 08/730,496, when it is desired to form curved or diagonal blood flow passageways to minimize turbulence and to promote substantially laminar blood flow through the passageway  
15 and into the bypass vessel.

Figure 13 shows a connector apparatus 10, which has the configuration of the specific apparatus 10k shown in Figure 7d, disposed within a transmyocardial passageway formed between a coronary blood vessel CBV  
20 and the left ventricle LV of the heart. In this manner, Figure 13 serves as an example of an application wherein any or all of the connector apparatus 10 of the present invention may be used to form a connection between anatomical structures other  
25 than two blood vessels (i.e., a coronary blood vessel and a chamber of the heart).

xiii. Possible Modification of Embodiments to Accommodate or Conform to Passageways of Differing Length

30 It will be appreciated by those skilled in the art that the length or distance between the first and second anatomical structures may vary considerably. Thus, for embodiments of the connector apparatus 10 which are of fixed length, it may be desirable to  
35 manufacture or provide such connector apparatus in a variety of lengths and sizes so as to allow the operator to select the appropriate length or size for

-40-

use in the instant application. Alternatively, many if not all of the embodiments of the present invention may be constructed such that the connecting portion of the connector apparatus 10 is elastic, adjustable, telescoping, distendable, of according configuration, or otherwise adjustable to accommodate or conform to passageways of differing length.

xiv. Delivery and Implantation of the Connector Apparatus

- 10 It should be generally understood that the connector may be delivered via any number or possible delivery mechanisms including but not limited to:
1. Delivery mechanisms which trap the connector initially within an inner tubular member and an  
15 outer tubular member wherein movement of the one member relative to the other allows the connector to be exposed and deployed at first partially to allow the first set of engagement members to come in contact with the first lumen and then deployed  
20 fully to allow the second set of engagement members to come into contact with the second lumen.
  2. Connectors which are mounted onto a balloon, covered or non-covered by a temporary sheath, and  
25 then deployed with the assistance or forcibly directed by the balloon to their engaging position.
  3. Connectors mounted between two balloons, initially covered or non-covered by a sheath, wherein the  
30 balloons act principally to bring the engagement members into contact with the apposing lumens; however, the two balloons may further act to dilate and further deploy the connector within the channel.
  - 35 4. Two piece connectors, such as the rivet device shown in Figure 6, may be deployable via two members mounted over a central core capable of

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moving towards each other such that the resultant force acts to engage the inner aspect of the two rivet components, fixing them in apposition.

- 5 5. Delivery mechanisms which hold the connector in a compressed state within a sheath and deploy the connector through the relative movement of an inner push-rod mechanism, allowing it to deploy in a first partially expanded state, and then to a fully expanded state.
- 10 6. Delivery of connectors which may be rotationally inserted into the tissue, expanding it as it is advanced into position, and then disengaged, allowing the connector to remain anchored within the channel that was partially enhanced by the delivery mechanism.
- 15 7. Delivery mechanisms which utilize some form of thermal, electrical, fluid or chemical means to induce a conformational change in the connector upon proper positioning in the channel.
- 20 Examples of suitable delivery catheters for implanting connector apparatus 10 of the present invention are shown in Figures 14a-14d.

Figure 14a shows a withdrawable sheath type delivery catheter 100a comprising an elongate inner member 102 having a connector apparatus 10 of the present invention mounted thereon, and a surrounding retractable outer sheath 104. The connector apparatus 10 in this embodiment is preferably self-expanding or formed of shape memory material which will radially expand when warmed to body temperature. When the sheath 104 is fully advanced over the connector apparatus 10, the sheath will radially constrain and hold the connector apparatus 10 in the desired radially compact configuration. After the catheter 100a has been advanced to the desired location, the sheath 104 may then be retracted (or alternatively the inner member 102 may be advanced) thereby removing the

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surrounding constraint from the connector apparatus 10 such that the connector apparatus 10 may radially expand and become implanted in the desired location.

Figure 14b shows a balloon delivery catheter 100b comprising a tubular catheter body 106 and an elongate member 108 having an inflatable balloon 110 formed thereon. The connector apparatus 10 is initially mounted on the deflated balloon 110 with the connector apparatus 10 in its radially compact configuration. After the catheter 100b has been advanced to the desired implantation site, the catheter 106 is withdrawn (or the inner member 108 is advanced) and the balloon is inflated so as to radially expand the connector apparatus 10 and to cause the connector apparatus to become implanted at its desired implantation site.

Figure 14c shows a push rod type delivery catheter 100c comprising an outer tubular sheath 112 and an advanceable push rod 114. The connector apparatus 10 is initially placed in the lumen of the catheter sheath 112, ahead of the distal end of the push rod 114, with the connector apparatus 10 in its radially compact configuration. After the catheter 100c has been advanced to the desired implantation site the catheter 112 may be retracted (or the push rod 114 may be advanced) to expel the connector apparatus 10 out of the distal end of the catheter. In this manner, the connector apparatus 10 is relieved of any surrounding constraint and is permitted to radially expand and become implanted in the desired implantation site. It will be appreciated that this embodiment is particularly suitable for self-expanding embodiments of the connector apparatus 10 or those formed of shape memory material which will expand upon warming to body temperature. A more detailed description of this push rod type of delivery catheter is set forth in parent

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application Serial No. 08/730,327, filed on October 11, 1996.

Figure 14d shows a slider sheath type delivery 100d. This device comprises an inner member 120 upon which the connector apparatus 10 is mounted in its radially compact configuration. Proximal and distal sheaths 122a 122b are initially drawn together such that the distal end of the proximal sheath member 122a is in abutment with the proximal end of the distal sheath member 122b, thereby covering and providing an enclosure or constraint about the radially collapsed connector apparatus 10. After the catheter 100b has been advanced to the desired implantation site, one or both of the proximal and distal sheath member 122a, 122b is/are moved away from the other so as to expose the radially compact connector apparatus 10, as shown in Figure 14b. In embodiments where the connector apparatus 10 is self-expanding or formed of shape memory material which will expand upon warming to body temperature, such opening of the slider sheaths 122a, 122b will allow the connector apparatus 10 to expand and become implanted at its desired implantation site. In other embodiments wherein the connector apparatus 10 is formed of plastically deformable material, the radial expansion member such as an inflatable balloon will be mounted on the inner member 120 beneath the radially compact connector apparatus 10. Such radial expansion or balloon may then be radially expanded (e.g., inflated) to radially expand and plastically deform the connector apparatus 10, as desired.

Figure 14e shows a rotatable delivery catheter 100e which comprises an elongate member 130 which is in itself rotatable, or which is provided with a rotatable distal portion. The connector apparatus 10 is mounted upon the distal portion of the elongate member 130, as shown. After the elongate member 130 has been advanced to a position adjacent the desired implantation site,

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the elongate member 130 or the distal portion thereof is rotated, and the elongate member 130 is further advanced so as to rotatably drive and advance the connector apparatus 10 into the desired implantation site. It will be appreciated that this embodiment is particularly useable for connector apparatus 10 which are not radially expandable, and or those having helical or spiral ribs on the outer surface thereof (e.g., Figure 11c) and/or for those having a leading edge which is sharpened or otherwise adapted to cut tissue so as to bore and form or enlarge the passageway as the connector apparatus is advanced.

These additional connector delivery catheters shown in Figures 14a-14e are examples of the types of delivery catheter devices which may be utilized, in addition to the double balloon catheter shown in Figures 3''', 4''' and 5'', and described more fully hereabove.

xv. Connector Apparatus Which Include Tissue Puncturing Connecting Portions Such That The Connecting Portions May Reside Outside of The Fluid Flow Passageway

Figures 15a-15a' show a modified rivet type connector apparatus 10e''', of the type previously described and claimed in United States Patent Application Serial No. 08/730,327. This connector apparatus 10e''' comprises first and second annular engagement members 600, 602, and a plurality of connecting members 604 which extend from first engagement member 600 and which are adapted to engage and connect to receiving aperture 606 formed in the second engagement member 602. As shown in Figure 9a and 9a', the connector member 604 may be capable of penetrating through the tissue, and may be situated such that they will pass through the walls of the first and second blood vessels BV<sub>1</sub>, BV<sub>2</sub> and through any intervening interstitial tissue such that the connector

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members 604 will lay outside of the previously formed passageway or channel, and outside of the openings formed in the respective first and second blood vessels BV<sub>1</sub>, BV<sub>2</sub>.

5        These drawings illustrate that the connector portion of the connector apparatus 10 need not extend through or reside within the fluid flow passageway, but actually may protrude through intervening tissue and reside outboard of the passageway, as shown.

10        These delivery devices are generally capable of being advanced over a guide wire into the channel and may assist passively or actively in the proper deployment of the connector. Further it should be understood that various radiopaque or imageable markers  
15        may be placed in important locations on the delivery mechanism to permit proper placement or monitoring of placement during deployment. Further, it is also possible that various recapturing mechanisms such as thread(s), hood(s) or other capturing or securing means  
20        may be provided to allow for the reversible deployment of the connector in the instance where it was found to be improperly placed.

      The invention has been described hereabove with reference to certain presently preferred embodiments  
25        only, and no effort has been made to exhaustively describe and show all possible embodiments in which the invention may take physical form. Indeed, numerous alterations, modifications and changes may be made to the above-described embodiments without departing from  
30        the spirit and scope of the invention. For example, specific elements or attributes of one embodiment may be incorporated into any or all of the other embodiments shown in the drawings, and may be interchanged or recombined in any possible  
35        combinations, and all such modifications and combinations of the elements and components of the

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invention described herein are intended to be within  
the scope of the following claims.

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## WHAT IS CLAIMED IS:

1. An apparatus for connecting a first opening formed in a first anatomical structure to a second opening formed in a second anatomical structure said first anatomical structure having an inner space which is defined at least in part by a first inner surface, and said second anatomical structure having an inner space which is defined at least in part by a second inner surface, said apparatus comprising:
  - a) a first engagement portion which is engageable with the first anatomical structure adjacent the first opening formed therein;
  - b) a second engagement portion which is engageable with the second anatomical structure, adjacent the second opening formed therein;
  - c) a connecting portion which connects said first engagement portion and said second engagement portion, said connecting portion being configured to hold said first and second openings relative to each other.
2. The apparatus of Claim 1 wherein said connecting portion is a tubular member.
3. The apparatus of Claim 1 wherein said connecting portion is a wire member.
4. The apparatus of Claim 3 wherein said wire member is of a helical configuration.
5. The apparatus of Claim 1 wherein said connecting portion comprises a frame which will maintain an open passageway through surrounding tissue.
6. The apparatus of Claim 1 wherein said connecting portion is a mesh tube.
7. The apparatus of Claim 1 wherein said first engagement portion is a splayable member which is initially maintained in a non-splayed configuration and, after being positioned adjacent the first opening formed in the first anatomical structure, is convertible to a splayed configuration wherein said

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first engagement member will engage the inner wall of the first anatomical structure adjacent the first opening formed therein.

8. The apparatus of Claim 1 wherein said second  
5 engagement portion is a splayable member is initially maintained in a non-splayed configuration and, after being positioned adjacent the second opening formed in the second anatomical structure, is convertible to a  
10 splayed configuration wherein said second engagement member will engage the inner wall of the second anatomical structure adjacent the second opening formed therein.

9. The apparatus of Claim 7 wherein said first  
15 engagement member is self-splaying and resiliently biased to its splayed configuration.

10. The apparatus of Claim 8 wherein said second engagement member is self-splaying and resiliently biased to its splayed configuration.

11. The apparatus of Claim 7 wherein said first  
20 engagement portion is plastically deformable and is initially formed in its non-splayed configuration, and is subsequently deformable to its splayed configuration by exertion of pressure against said engagement member.

12. The apparatus of Claim 8 wherein said second  
25 engagement portion is plastically deformable and is initially formed in its non-splayed configuration, and is subsequently deformable to its splayed configuration by exertion of pressure against said engagement member.

13. The apparatus of Claim 1 wherein said  
30 apparatus is initially deployable in a radially compact configuration, said apparatus being subsequently radially expandable to an operative configuration wherein at least said first and second engagement portions will abut against and engage the adjacent  
35 surfaces of the first and second anatomical structures.

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14. The apparatus of Claim 13 wherein said apparatus is self-expanding and resiliently biased to its operative configuration.

15. The apparatus of Claim 13 wherein said apparatus is plastically formable and is initially formed in its radially compact configuration, and is subsequently deformable to its operative configuration by exertion of radial pressure upon said apparatus.

16. The apparatus of Claim 1 wherein said apparatus is a hyperboloidal helical coil.

17. The apparatus of Claim 16 wherein said hyperboloidal helical coil is formed of a multiplicity of adjacent convolutions of wire, and wherein at least some of said adjacent convolutions are fused to one another.

18. The apparatus of Claim 1 wherein said first and second engagement portions comprise frusto-conical helical coils having outer and inner ends, the outer ends of said helical coils being larger in diameter than the inner ends thereof.

19. The apparatus of Claim 18 wherein said connecting portion of said apparatus comprises a tubular member mounted between and connecting the inner ends of said frusto-conical helical coils.

20. The apparatus of Claim 1 wherein said apparatus is a tube having inwardly arched side walls such that the ends of the tube are of larger diameter than the middle of the tube, said ends of the tube thereby forming said first and second engagement portions, and said middle of the tube thereby forming said connecting portion.

21. The apparatus of Claim 20 further comprising:  
at least one splayable engagement member  
formed on each end of the tube.

22. The apparatus of Claim 21 wherein said at least one splayable engagement member is self-splaying

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and resiliently biased to an outwardly splayed configuration.

23. The apparatus of Claim 21 wherein said at least one engagement member is plastically deformable, and initially formed in a non-splayed configuration but subsequently deformable by exertion of outwardly directed pressure thereagainst.

24. The apparatus of Claim 20 wherein said tube is a solid tube.

25. The apparatus of Claim 20 wherein said tube is mesh tube.

26. The apparatus of Claim 20 wherein said tube is formed of a material selected from the group of materials consisting of:

- a helical wire coil;
- a helical filament coil;
- wire mesh;
- a shape memory alloy;
- plastic;
- metal;
- woven fabric;
- elastic material; and,
- elastomeric material.

27. The apparatus of Claim 1 wherein said apparatus comprises a plastic structure wherein the connecting portion comprises a tube, and wherein a first and second engagement portions comprise projections which extend laterally outward from opposite ends of said tube.

28. The apparatus of Claim 1 wherein said apparatus comprises a wire clip, wherein said first and second engagement portions comprise wire projections which extend laterally outward from the center of the clip, and wherein said connecting portion comprises traversing segments of wire which extend between said projections.

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29. The apparatus of Claim 1 wherein said apparatus comprises an elongate member having a series of generally sinusoidal bends formed therein, and first and second ends, the first and second ends of said wire member being joined to one another to form a ring, and at least some of said sinusoidal bends being turned outwardly therefrom to form projections which extend outwardly from said ring, said projections thereby forming said first and second engagement portions, and said ring thereby forming said connecting portion.

30. The apparatus of Claim 29 wherein said sinusoidal bends include a plurality of first sinusoidal bends of a first amplitude, and a plurality of second sinusoidal bends of a second amplitude, said second amplitude being larger than said first amplitude, said second sinusoidal bends of said second amplitude being bent outwardly to form said projections, and said first sinusoidal bends of said first amplitude remaining without outward bending so as to form said ring.

31. The apparatus of Claim 1 wherein said apparatus comprises a triplet coil connector comprising:

a first helical coil having a first longitudinal axis, a second helical coil having a second longitudinal axis which is not parallel to the first longitudinal axis, and a third helical coil having a third longitudinal axis, said third longitudinal axis being perpendicular to said second longitudinal axis but spaced apart from said first longitudinal axis;

said triplet coil connector being thereby implantable within the body such that the first helical coil is within the inner space of the first anatomical structure, said third helical coil is within the inner space of the second anatomical structure, and said second helical coil

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extends between said first and second openings in said first and second anatomical structures.

32. The apparatus of Claim 31 wherein said first, second, and third coil members are formed of helically wound wire.

33. The apparatus of Claim 31 wherein said first, second, and third coil members are formed of helically wound filament.

34. The apparatus of Claim 1 wherein said connector apparatus is a flanged tube connector wherein said connecting portion comprises a tube, and wherein said first and second engagement portions comprise semi-cylindrically shaped flanges which extend laterally outward from opposite ends of the said tube.

35. The apparatus of Claim 34 wherein said flanged tube connector is formed by a method comprising the steps of:

a) providing a tube having a longitudinal axis, a cylindrical side wall disposed about said longitudinal axis, first and second ends, and a hollow lumen extending longitudinally therethrough;

b) forming first and second rectangular notches at directly opposite locations in the first end of said tube, said rectangular notches having side edges which are parallel to said longitudinal axis, and an end which is perpendicular to said longitudinal axis;

c) forming third and fourth rectangular notches at directly opposite locations in the second end of said tube, said rectangular notches having side edges which are parallel to said longitudinal axis, and an end which is perpendicular to said longitudinal axis;

d) forming first and second generally arcuate notches at directly opposite locations in the cylindrical side wall of the tube, in

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alignment with the ends of the first and second rectangular notches;

e) forming third and fourth generally arcuate notches at directly opposite locations in the cylindrical side wall of the tube, in alignment with the ends of the third and fourth rectangular notches; and,

f) outwardly bending the remaining cylindrical side walls of the tube adjacent said rectangular notches such that said generally arcuate notches become substantially closed, and said outwardly bent portions of the side wall form semi-cylindrical flanges which protrude outwardly from opposite ends of the remaining mid-portion of the tube, generally perpendicular to said longitudinal axis.

36. The apparatus of Claim 1 wherein said connecting portion is configured to extend through and reside within a passageway formed between said first and second openings.

37. The apparatus of Claim 1 wherein said connecting portion is constructed to penetrate through tissue and is positioned to reside within surrounding tissue and outboard of a passageway which has been formed between the first and second openings.

38. The apparatus of Claim 1 wherein said apparatus is adapted to transmit energy to tissue with which the apparatus comes into contact, thereby providing an energy-mediated treatment to said tissue.

39. The apparatus of Claim 1 wherein said first and second engagement portions comprise annular members, and wherein said connecting portion comprises:

at least one connector member formed on said first engagement portion and adapted to insert into an engaged said second engagement portion when said first and second engagement portions are moved toward one another.

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40. The apparatus of Claim 39 wherein said connector portion comprises at least one elongate member.

5 41. The connector apparatus of Claim 1 wherein said apparatus further comprises at least one magnet to facilitate connection of the first engagement portion to the second engagement portion.

10 42. The connector apparatus of Claim 1 wherein said connecting portion comprises scaffolding to deter in growth into the passageway formed between the first and second anatomical structure.

15 43. The connector apparatus of Claim 1 wherein said connector has a leading edge, and wherein said leading edge is adapted to sever tissue as said connector is advanced.

44. The connector apparatus of Claim 1 wherein said connector has an outer covering which is selected from the group of outer coverings consisting of:  
20 a synthetic tube graft;  
a natural tube graft;  
a chemical coating;  
an antithrombogenic coating;  
a thrombolytic coating; and,  
an antimicrobial coating.

25 45. The connector apparatus of Claim 1 wherein said connector further comprises at least one radioactive material to deter tissue ingrowth following implantation.

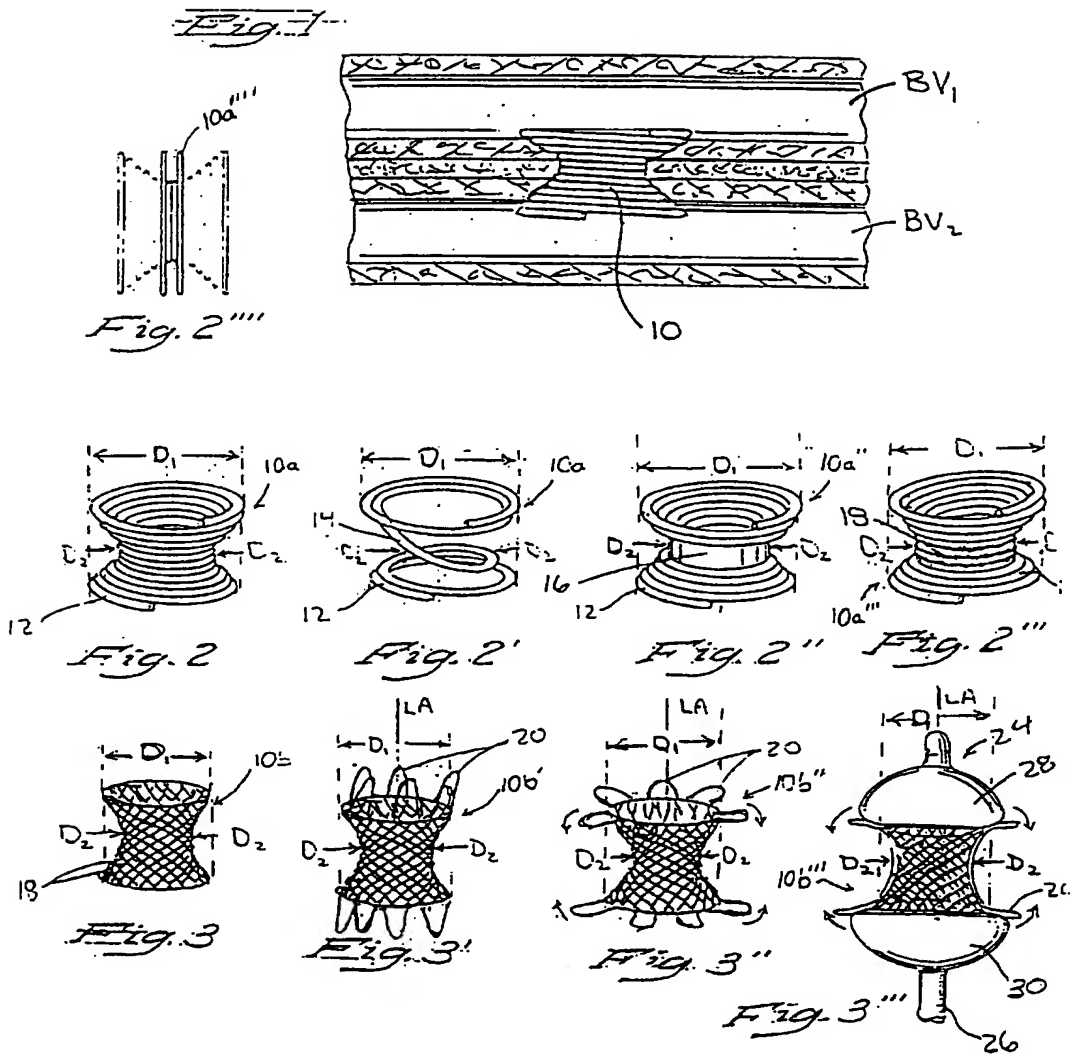
30 46. The connector apparatus of Claim 1 wherein said connecting portion is constructed to pull said first and second engagement portions toward one another.

35 47. The connector apparatus of Claim 46 wherein said pulling of the first and second engagement members toward one another enables the connector apparatus to form connections between anatomical structures which are separated by varying distances.

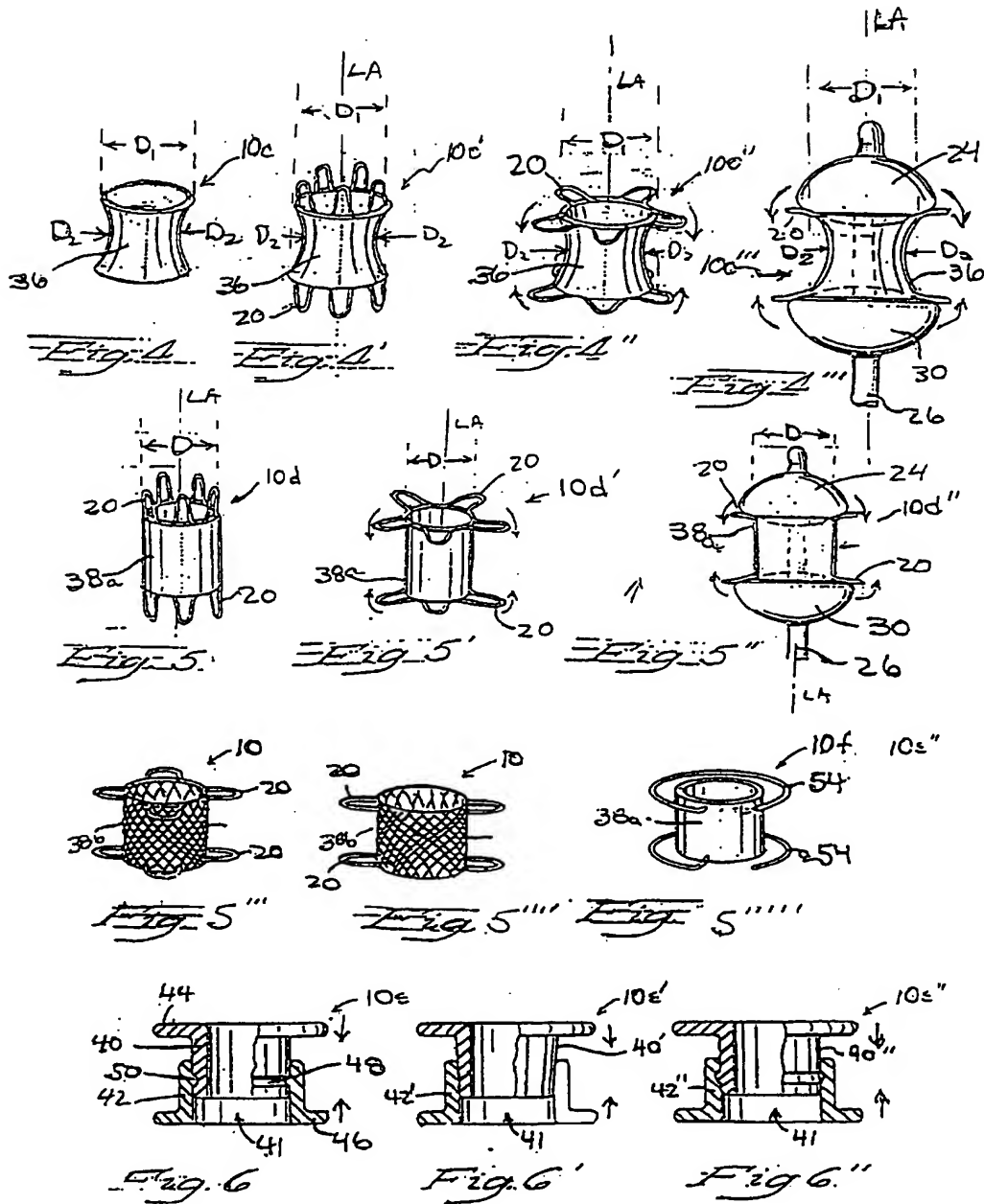
-55-

48. The connector apparatus of Claim 46 wherein said pulling of the first and second engagement members toward one another serves to minimize the length of the channel wherein the connector apparatus is implanted.

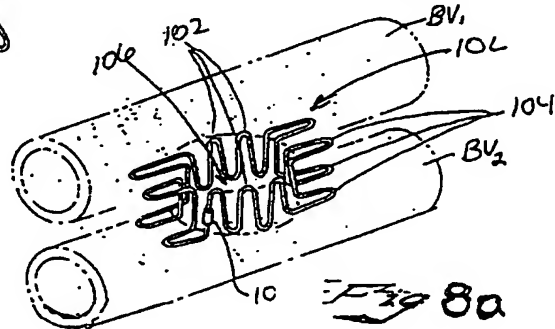
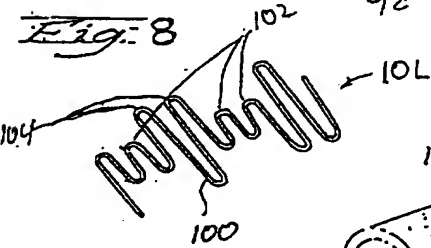
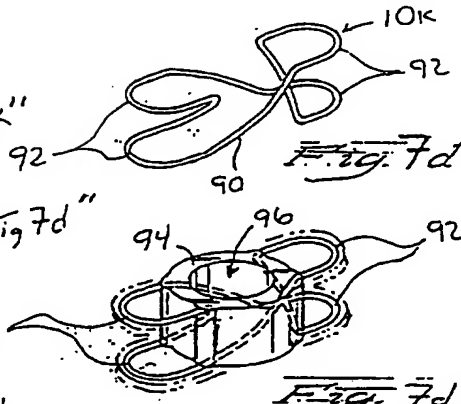
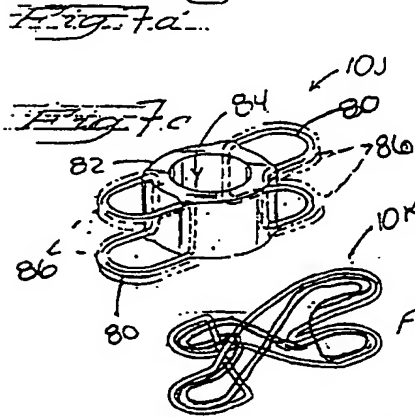
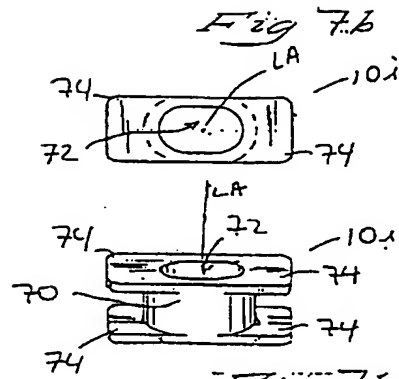
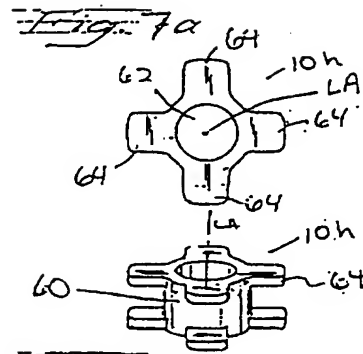
- 5        49. The connector apparatus of Claim 1 wherein the connecting portion of the apparatus is constructed to maintain a passageway of a predetermined minimum diameter between the first and second openings formed in the first and second anatomical structures.



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3/7



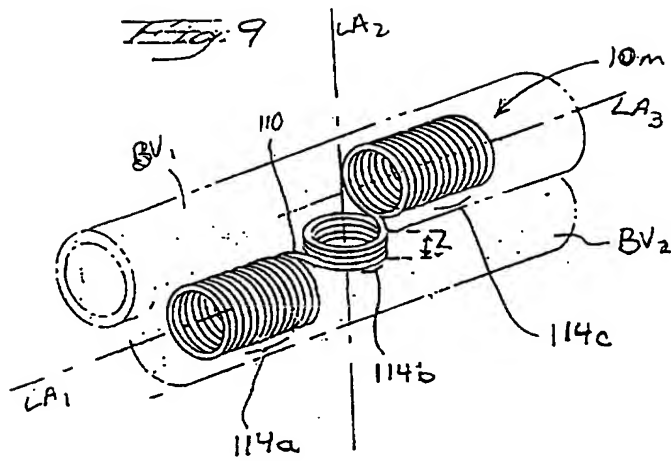
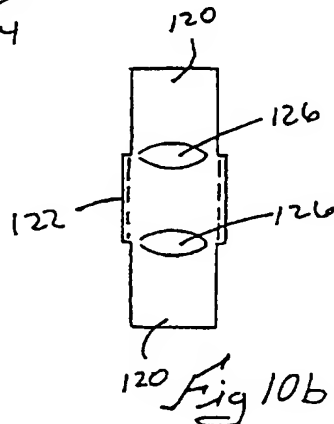
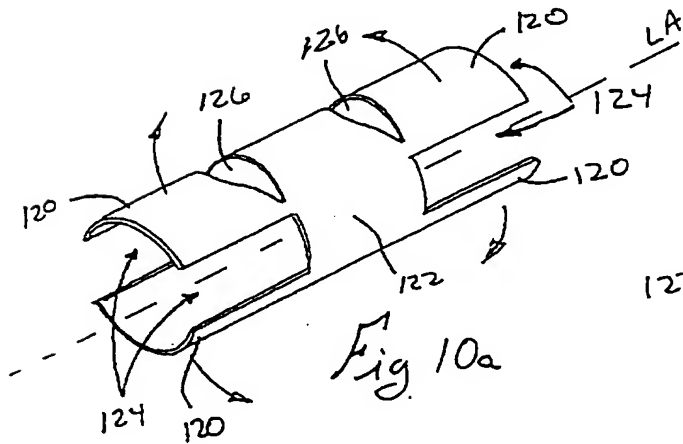
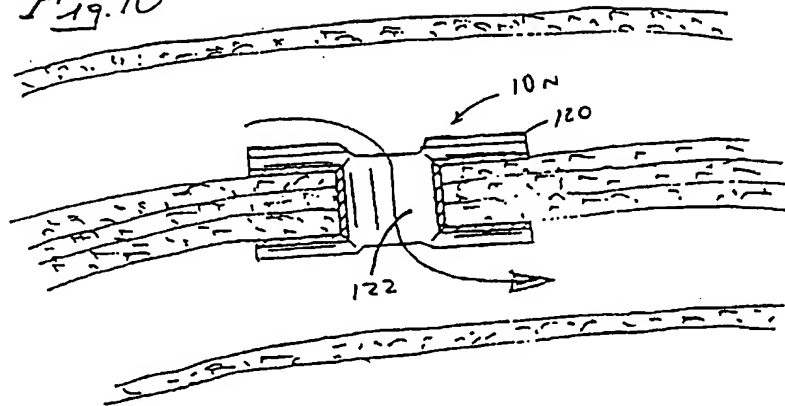


Fig. 10



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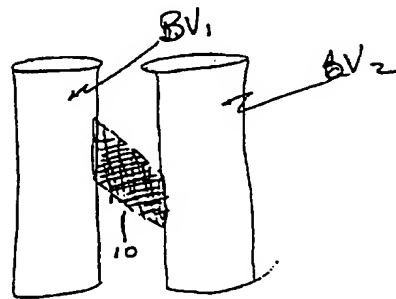
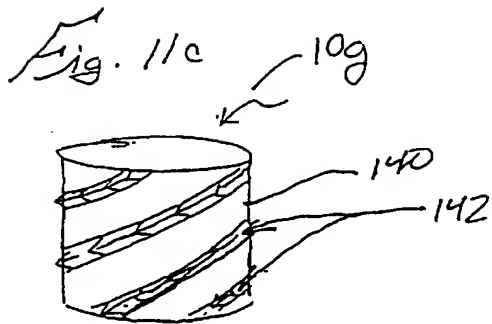
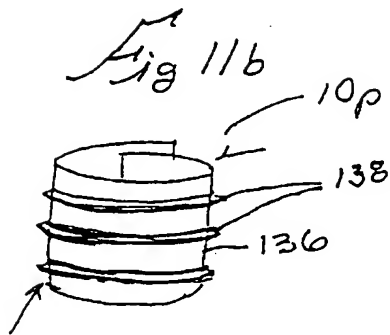
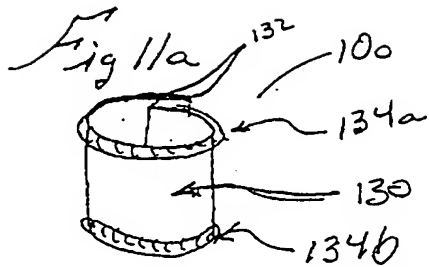


Fig 12

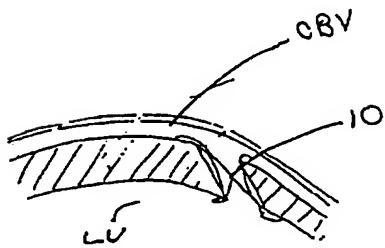
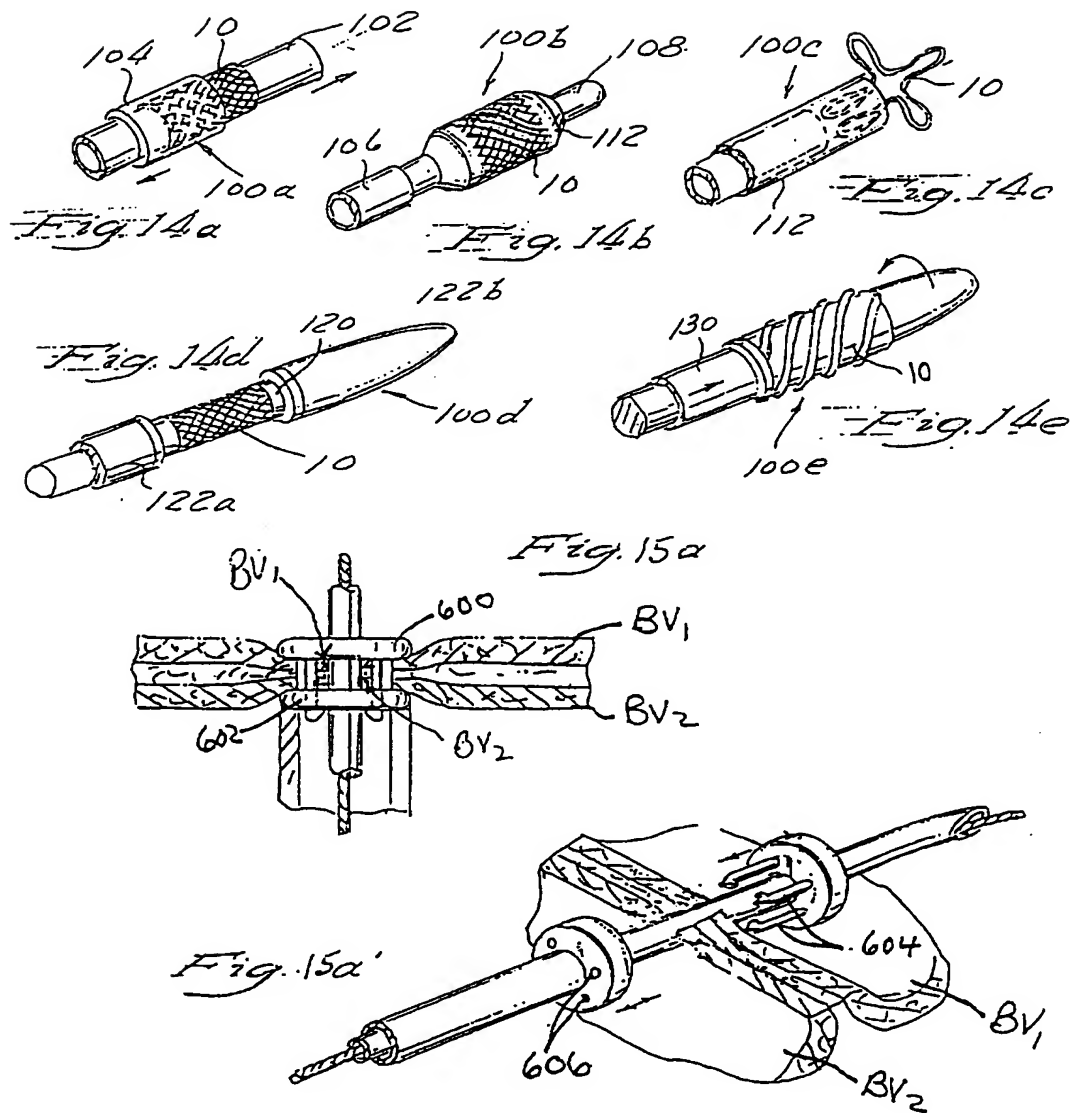


Fig 13



## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US97/01468

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61M 29/00

US CL : 606/198

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/1, 108, 152-156, 192, 194, 195, 198, 200; 623/1, 12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,383,892 A (CARDON et al.) 24 January 1995, entire document.	1-45
X	US 5,466,242 A (MORI) 14 November 1995, entire document.	1-45

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

## \* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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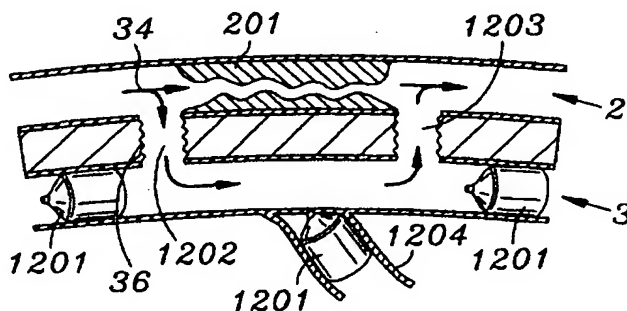
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(57) Abstract

Method and apparatus for utilizing the vascular system as a conduit to reach other vascular and extravascular locations within the body. Included are methods for revascularization wherein the extravascular passageways are formed to permit blood flow between vascular locations. Also included are methods for performing transvascular interstitial surgery (TVIS) wherein extravascular passageways are formed from a blood vessel to another vascular or non-vascular intracorporeal location. Also disclosed are devices usable for forming extravascular passageways in accordance with the invention, or for modifying, valving, maintaining or closing such passageways.

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A DEVICE, SYSTEM AND METHOD FOR INTERSTITIAL  
TRANSVASCULAR INTERVENTION

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Background of the Invention

Percutaneous Transvascular Arterial Bypass

Atherosclerosis is a progressive disease process in which the flow within  
10 the lumen of an artery becomes restricted by a blockage, typically referred to as  
an atherosclerotic plaque. In the heart, as well as the periphery, a blockage of an  
artery can result in pain, dysfunction and even death. Numerous methods have  
been employed over the years to revascularize the tissue downstream of an  
arterial blockage. These methods include bypass grafting - using artificial, in-  
15 situ venous, or transplanted venous grafts, as well as angioplasty, atherectomy  
and most recently, laser transmyocardial revascularization. Bypass grafting has  
been extremely successful; however, the procedure requires extensive surgery.  
Recently, newer techniques such as the transthoracic endoscopic procedure being  
pursued by the company, Heartport, Inc. and Cardiothoracic Systems, Inc.,  
20 illustrate the need for a less invasive method of bypassing coronary vessels.  
These procedures are very difficult to perform, and may not be widely  
applicable. While transmyocardial laser revascularization, a technique in which  
small holes are drilled through the wall of the heart, looks promising, the  
method of action is not yet well understood, and problems exist with the use of  
25 laser energy to create the channels. Yet clinicians are still very interested in the  
technique because it has the potential to be minimally invasive, and does not  
require the patient to be placed on cardiopulmonary bypass.

In the 1970s several cardiovascular surgeons experimented with the use of  
cardiac veins for revascularization. The procedure was for use on patients which  
30 had severely diffuse stenotic coronary vessels. The technique involved using an  
intervening graft from the internal mammary artery or an aortic attachment to a

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saphenous vein. Instead of sewing the grafts to the distal coronary artery, the grafts were attached to the coronary or cardiac vein in the same location. The proximal portion of the vein was then ligated to prevent a shunt, and the patient was then taken off cardiopulmonary bypass, and chest was closed. In this

5 model, the vein were 'arterialized', allowing flow in a retrograde fashion in a effort to bring oxygenated blood to the venules and capillaries of the heart. The success of this technique varied greatly, and was for the most part abandoned. Problems included stenosis at the anastomosis, intracardiac hemorrhages from ruptured venules, and thrombosis of the grafts.

10 The devices, systems and methods proposed in this disclosure suggest a new method of percutaneous revascularization. Here, the cardiac veins may either be arterialized, or may be simply used as bypass grafts. There is no literature to suggest that this has been ever been attempted. While in-situ bypass grafts have been made in the periphery, still an incision is made to attach and

15 ligate the vein ends. Another procedure which bears some resemblance to this technique is called the TIPS procedure - transjugular intrahepatic portosystemic shunt. In this procedure a stent is advanced into liver tissue to connect the portal vein to the inferior vena cava. While this procedure can be accomplished percutaneously, it is not for the purpose of revascularization of an organ or to

20 bypass a blockage within a vessel, does not permit retrograde flow within either of the two vessels, is not performed with an accompanying embolization, and requires the use of a stent. Further, the devices and methods used in that setting are too large and do not have the directional capability necessary for use in smaller vessels such as those found in the heart.

25 Transvascular Intervascular Interstitial Surgery

Open surgery was for many years the only way to gain access to tissues to perform a surgical maneuver. With the advent of optics, various endoscopic procedures were developed. Initially, these procedures utilized natural orifices such as the urinary tract, oral cavity, nasal canal and anus. Most recently, new

30 techniques using transabdominal and transthoracic ports have been developed. These thorascopic or laparoscopic procedures essentially use instruments which

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are long-shafted versions of their counterparts in open surgery. General anesthesia is usually required, and there are still several smaller wounds which require healing.

Another problem that exists with this approach is the identification of anatomically consistent reference points. For precise surgery, such as in the brain, a frame is usually attached to the patients head to provide this reference. More recently, a 'frameless' system has been developed which utilizes a much smaller frame mounted with several light emitting diodes (LEDs). The LEDs are correlated to LEDs on the instrument itself using three cameras mounted to the ceiling. This aid in the correlation of the frame to the landmarks, and assures proper positioning of the instrument. While this seems like an extensive effort, it underlines the importance of gaining access to the exact location desired.

Traditionally, the vascular system has been entered for the sole purpose of addressing a vascular problem. Angioplasty, atherectomy, stents, laser angioplasty, thrombolysis and even intracardiac biopsy devices have all been designed for intravascular use.

#### Summary of the Invention

A device, system and method are provided for utilizing the vascular system as a conduit through which an intervention can be rendered within and beyond the vascular wall. In accordance with one embodiment, a device is introduced into the vascular system at a convenient entry point and is advanced to a particular target location at which point an opening is created to allow the passage of the device or another a device or devices through or around the port into the space beyond the interior of the vessel. In one embodiment, a system is used to act as an access port to the space through which a procedure may be performed. Such a procedure may be used worthwhile for cooling or ablating a volume of tissue, injecting or infusing a drug, substance or material, cutting, manipulating or retrieving tissue, providing access for endoscopic visualization or diagnosis, the placement of an implantable or temporary device, creating an alternative tract through which blood may be conducted for the purpose of revascularization or for performing some other surgical procedure. In another

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embodiment, the system is used to achieve an opening in an adjacent vessel proximate to the first opening to allow the passage of blood through the channel created by the device. Such a procedure may be useful for creating alternative vascular channels to provide alternative revascularization routes, such as in the heart between the coronary arteries and cardiac veins. With further specificity, such a system may be used to bypass coronary arteries and provide for cardiac venous arterialization, or segmental grafting. In addition, the stability of vascular supply orientation to anatomic landmarks provides a simple method of repeatedly accessing perivascular structures under imaging or other guidance. This may be particularly useful for accessing areas within the brain, kidney, lung, liver, spleen as well in other tissues, and represents a significant advantage over tissue marking localization, external frames or so-called "frameless" external instrument orientation systems. In a final embodiment, the system is used to create an opening in the vessel proximally, tunneling through the tissue adjacent to the vessel, and re-entering the vessel at a distal point. This may be useful for providing an alternate path for blood flow around a lesion with a vessel.

#### Detailed Description of the Preferred Embodiments

The invention herein utilizes the vascular system as a perfect conduit to any region of the body. The devices, systems and methods described here provide a new way that the interstitial space can be accessed for surgical purposes. The invention described herein provides a system for gaining percutaneous access to any part of the body through the vascular system, and provides the basic set of instrumentation for accomplishing several surgical and medical end-points.

The present invention provides a percutaneous means for revascularizing an organ fed by a diseased vessel. In accordance with further embodiments of the present invention, a complete multiple coronary artery bypass may be accomplished without cracking open the chest, general anesthesia or cardiopulmonary bypass.

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In order to provide an overall understanding of the present invention, the method of the invention will be discussed with reference to the device's use to bypass a lesion within the coronary artery in the heart percutaneously.

However, it will be understood by persons of ordinary skill in the art that the

5 general method, system and device as described herein are equally applicable to the surgical manipulation of any perivascular structures. This invention represents a new concept in minimally invasive surgery which is that the vascular system may be used purely as a conduit to a desired surgical point. Under the proper guidance, at that surgical point, the perivascular space can be  
10 penetrated by a device so as to allow for the insertion of various instrumentation to effect a surgical effect. Some examples of these procedures may include but are not limited to: transvascular intracranial access and subsequent therapeutic or diagnostic intervention to various perivascular tumors, hemorrhages, stroke-affected areas and diseased zones; transvascular tissue biopsies from the brain,  
15 heart, kidney, liver, lung or bone; transvascular implantation of drugs, materials or devices such as sensors, radioactive seeds, ferromagnetic particles, balloons, cells or genetic material.

Referring to FIG. 1, a typical coronary sinus guide catheter 4 is shown having been advanced up the vena cava 7 and into the heart 1. Although not  
20 shown, the guide catheter 4 has been advanced into the coronary sinus within the right atrium of the heart 1. This guide catheter will be of the type generally known in the art to include a tip of sufficient compliance and size to assure atraumatic insertion into the coronary sinus, with a balloon at its distal end to permit the retrograde injection of contrast to permit imaging of the cardiac  
25 venous system. The transvascular interstitial surgery (TVIS) guide catheter 5 is inserted through the guide catheter and advanced through one cardiac vein 3 over a guide wire 28 to a desired point adjacent to a coronary artery 2. The figure shows a TVIS probe 27 being advanced through the TVIS guide catheter 5 through an opening in the cardiac vein 3 to a desired point in the coronary artery  
30 2.

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FIG. 2 shows in more detail the various functions and components which could be included on the TVIS guide catheter 5. Here the TVIS guide catheter 5 is shown within a cardiac vein 3 being advanced over guidewire 28. A balloon 21 is provided on TVIS guide catheter 5 for the purpose of blocking flow, stabilizing the catheter within the lumen, or dilating the passageway. TVIS guide catheter 5 is also provided with either or both active orientation detection means 23 and passive orientation detection means 22. Persons of ordinary skill in the art could identify that the passive orientation means 22 may be configured of any of a known set of materials which would allow for the radiographic, fluoroscopic, magnetic or sonographic detection of the position and orientation of the distal portion of the TVIS guide catheter 5 within the body. These materials include but are not limited to any radiopaque material such as barium or steel, any ferromagnetic material such as those with iron, or any material or composite which provides sufficient interference to sound waves such as trapped air bubbles, scored metal or several laminates. The active orientation detection means 23 permits the proper 360 degree orientation of the distal portion on the TVIS guide catheter 5 within the lumen of the vessel, in this case cardiac vein 3. This active orientation means 23 can utilize any one but is not limited to one of the following technological schemes: the active orientation means 23 may be a simple piezo-electric, wire or silicon based slab capable of sending and receiving a signal to detect the presence or velocity of flow within an adjacent vessel; this same device could be an array of receivers in relationship to a transmitter for the purposes of providing an image of the surrounding tissue; this same device could also be a simple transmitter capable of sending a signal to guidewire 202 positioned in this case within the coronary artery 2 - where guidewire 202 is further modified to include a small receiver/transmitter 203 and wire bundle 204 capable of returning a signal to the operator upon detection of the signal emitted by active orientation means 23; the reverse system is also applicable where the small receiver/transmitter 203 sends a signal to active orientation means 23; the same could also be said for orientation means 23 to send or receive signals to or from any of a series of known signal generators including sonic, electromagnetic,

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light or radiation signals. The TVIS guide catheter 5 is provided in this case with an additional opening to allow for the selective injection of contrast or fluid into the vessel, in this case cardiac vein 3. Once the orientation of the TVIS guide catheter 5 is assured, the TVIS probe 27 and TVIS sheath 26 may be advanced  
5 through the wall of the cardiac vein 3 into the interstitial space 29 and into the coronary artery 2. The TVIS probe 27 and TVIS sheath 26 do not necessarily need to be advanced simultaneously and may have the following configurations: the TVIS sheath 26 may be a sharp tipped or semi-rigid cannula capable of being inserted into the tissue alone; the TVIS probe 27 may be a relatively rigid wire,  
10 antenna, light guide or energy guide capable of being inserted into the tissue alone with the support of TVIS sheath 26; or further the TVIS probe 27 and TVIS sheath 26 may be operatively linked where the two are inserted together into the tissue. The TVIS probe 27 and/or the TVIS sheath 26 provide the initial connection between the two vessels, the cardiac vein 3 and coronary artery 2.  
15 Once the TVIS sheath 26 is placed, a more floppy guidewire can be placed through it to permit the advancement of additional instrumentation in the case where another lumen is to be entered. Alternatively, no guidewire may be necessary if the interstitial space is being entered to perform a different type of procedure. This procedure may be used to create a bypass path from coronary  
20 artery 2 around a coronary stenosis 201, into the cardiac vein 3 and in some cases, back into the coronary artery 2.

To prevent coronary blood from shunting directly back into the right atrium through the coronary sinus, it is necessary to block flow at one or more points within the cardiac vein. Referring to FIG. 3, once the hole is made, and it  
25 is determined that it is of sufficient size, an embolization device, such as an embolization balloon 33, can be used to block flow in the cardiac vein 3 in a region proximal to tissue track 36. This maneuver ensures that coronary arterial flow 34 passes through tissue track 36 and results in a retrograde cardiac venous flow indicated by arrows 35a and 35b. The embolization balloon 33 is placed  
30 using embolization catheter 31 and upon proper inflation, is detached via a detachable segment 32. Those skilled in the art will recognize that any one of

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several devices and materials are available for the purpose of embolization. These include detachable balloons, coils, strands of coagulation producing material, microfibrillar collagen, collagen sponge, cellulose gel or sponge such as Gelfoam (TM), or special stents. FIG. 3 shows how these devices can be used to re-arterialize the venous system distal to the connection. However, as shown in FIG. 12, it is possible to simply provide a bypass path by performing the same procedure in reverse in an appropriate downstream location. It should be mentioned that these embolization devices may also be used to block off any unwanted tributaries branching off from the cardiac vein. FIGS. 4 and 9 are described later in this document.

FIGS. 10A-10B and 11A-11B depict two additional schemes of embolization devices in accordance with the invention which also may have utility to accomplish the desired closure.

FIG. 10A depicts a compressed collagen sponge 101 located within an outer sheath 102, capable of being delivered over guidewire 51. Once the guidewire 51 is advanced into vessel which is to be embolized, outer sheath 102 is withdrawn over inner core 103 to permit collagen sponge 101 to expand into the vessel as seen in FIG. 10B. Once completely delivered, the guidewire 51 and the catheter assembly 102 and 103 are withdrawn, leaving the sponge in place.

FIG. 11A depicts a one-way valve stent 112. Membrane 111, disposed within the stent 112, is configured to be cylindrical at side 116, yet collapsed upon itself at side 113 to form a one-way valve. As seen in longitudinal section FIG. 11B, this allows flow in the direction of arrow 114 and the advancement of devices in this direction, but prevents flow in the direction of arrow 115 as well as preventing devices from entering from that direction. The one-way valve stent 112 can be easily placed over a catheter into the desired location and expanded to fit in position. Once the internal delivery catheters are removed, membrane 111 is allowed to collapse, instantly creating a valve-like action.

In a further embodiment, an embolization device may not be necessary, as shown in FIG. 4. A stent 41 is placed through tissue track 36 such that coronary portion 41a and venous portion 41b are positioned as shown. Stent 41 may be

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covered by a material, a dense mesh or a matrix of cells, such that coronary flow 34 cannot easily flow through the side wall of stent 41 towards stenosis 201, but instead is re-routed through stent 41 into cardiac vein 3 to produce retrograde cardiac venous flow 35. In this figure, the position of the stent suggests that the TVIS guide catheter had been placed within the coronary artery 2, and the tissue track 36 was created in the arterial to venous direction. This would allow for the proper positioning of a guidewire and subsequently the stent to allow for the device to be oriented in the arterial to venous direction. It should be clear that it is also possible for a similar stent to be placed downstream (in a location, for example, corresponding to region 1203 in FIG. 12 accessed through vein 3) from the venous to arterial direction to permit a complete bypass of the stenosis 201 in the coronary artery 2. Stent 41 must have the capability of being dimensioned such that proximal portion 41a and distal portion 41b may be expanded into shape which closely approximates the respective wall of the vessel into which it is placed. Alternatively, as shown in figure 4a, the stent 410 may be placed such that proximal portion 410a and distal portion 410b do not block flow, but simply act to maintain the dimensions of tissue track 36.

FIG. 5 shows how tissue track 36 can be dilated by a standard balloon 52 advanced over guidewire 51 for the purpose of ensuring that tissue track 36 is wide enough to receive the flow. Further, this step may be necessary to properly dimension the tissue track 36 prior to insertion of other devices such as the stent 41 seen in FIG. 4, or stent 410 seen in FIG. 4a.

A stent may not be necessary to maintain the size of tissue track 36 if enough material can be removed or ablated between coronary artery 2 and cardiac vein 3. In FIG 6, a vaporization catheter 63 is shown being advanced over guidewire 51. Here, energy 61 is delivered to the tissue track 36 through the distal portion 62 of the vaporization catheter 63 to create a properly dimensioned connection between artery and vein. Those skilled in the art will recognize that this vaporization catheter 63 may also be used to deliver thermal, cutting, welding or coagulative energy via several means including but not

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limited to laser, bipolar or monopolar radiofrequency (RF), microwave, ultrasound, hot-wire, or radiation.

Stents such as those shown in FIG.4 and 4a may be necessary to control dimensions of the tissue track 36 from expanding under pressure, or closing as a result of restenosis. Another method of maintaining the dimensions of tissue track 36 permanently or temporarily during the healing and remodeling process is shown in FIG. 7. Here a polymer stent 71 is shown covering the walls of tissue track 36. Such a polymer stent 71 may be placed either by insertion and dilation using a balloon catheter, or may be created in-situ using various methods known in the art and practiced by a company by the name of FOCAL (TM) located in Massachusetts. Such a polymer stent 71 may permit the temporary protection from the effects of restenosis or pseudoaneurysm formation, and may dissolve after a period of time to reduce the likelihood of any long-lasting tissue reaction effects.

It may be possible that the creation of a tissue track is undesirable, due to the high likelihood that problems such as restenosis or pseudoaneurysm complicate the procedure. This problem may be overcome using methods such as those shown in FIGS. 8, 9, 9a, 9b, 9c, 22, 22a and 23.

In FIG. 8, a welding catheter system is used which consists of proximal welding catheter 81 and distal welding catheter 86. After the tissue track is created through interstitial space 29 between cardiac vein 3 and coronary artery 2, guidewire 51 is inserted. Distal welding catheter 86 is then advanced over guidewire 51 and distal approximation balloon 89 is inflated. Subsequently, proximal welding catheter 81 may be advanced over the distal welding catheter 86. At that point, proximal approximation balloon 82 may be inflated, and the two balloons may be pulled into position, opposing the edges of the opening in the coronary artery 2 and cardiac vein 3. The approximation balloons and welding catheters may be equipped with one or more of the following components: intraweld electrodes 83, contralateral welding surfaces 87 and 88, return electrodes 85 and 84 and a thermocouple 801. In this configuration, bipolar RF energy may be used to weld the two vessel openings together without

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the need for additional mechanical attachment devices. Energy will be delivered either between the contralateral welding surfaces 87 and 88 or between the intraweld electrodes 83 and the return electrodes 85 and 84. In either case, the temperature of the local tissue in and around the approximated two openings is  
5 elevated to a desired temperature measured by thermocouple 801. This temperature is maintained for a certain amount of time during which time the tissue is fused. After fusion, the power is turned off, the balloons are deflated, and the apparatus is removed, leaving the two openings fused around their perimeter.

10 In FIG. 9 a mechanical stapling method is described to attach the two vascular openings. Stapling catheter 91 has outer sheath 96, optional heating coils 94 and 97, staples 95, and micromachine staple holders 93. Stapling catheter 91 is advanced through tissue track 36 until the device is well into the coronary artery 2. The outer diameter of the outer sheath 96 is sized to slightly dilate the  
15 tissue track 36 between the two vessels. Outer sheath 96 is pulled back until the full upper halves of staples 95 are exposed. This point of pull back is controlled at the proximal end of the catheter. The staples 95 are composed of either a spring-like material such as stainless steel, or super elastic alloy such that they spring into a curved position as seen in FIG. 9a. This effect may also be  
20 accomplished using shape memory materials such as nitinol and adding heat through coil 97. Once staples' 95 upper halves have achieved their curved state, the stapling catheter 91 can be withdrawn, as shown in FIG. 9B, allowing the tips of the staples 95 to seat into the circumference of the opening in the coronary artery 2. Now the outer sheath 96 can be fully withdrawn (as shown in FIG. 9B),  
25 permitting the lower halves of the staples 95 to seat into the inner aspect of the circumference around the opening of the cardiac vein. Again this effect can be created either passively upon release of the sheath, or actively using heat from heating coil 94. While the passive approach is more simplified, the active approach allows for the reversal of the device using an injection of cold saline.  
30 This may be desirable in cases where the seating of the staples 95 was not accomplished correctly. Finally, once the staples' placement is assured, they may

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be released by the micromachine staple holders 93 resulting in the configuration shown in FIG. 9C, wherein staples 95 cause the tissue 36 to be maintained in an open condition. Those skilled in the art will recognize that other than utilizing micromachines, there may be several methods of staple release, including

5 thermal material methods such as solder melting, thermal degradation of a retaining polymer or biomaterial, as well as mechanical methods such as the removal of a retaining wire, balloon expansion of a weak retaining material, or an unlocking motion of the stapling catheter 91 with respect to the staples 95 that could only be accomplished after the staples have been fixed in place.

10 FIG. 22 shows another embodiment for holding together the two openings in both vessels. This embodiment utilized a distal guide catheter 2205 which is inserted over a guide wire 2206. An upper clip 2204 is held to the distal guide catheter 2205 by a collapsible retaining unit 2207 located near the upper clip 2204. This assembly is advanced through tissue track 36 until it is completely

15 through. In this case, the collapsible retaining unit 2207 helps to dilate the tissue track 36 since the upper clip 2204 is dimensioned to be slightly larger than the diameter of tissue track 36. A proximal guide catheter 2201 with a lower clip 2202 at its tip are advanced over the distal guide catheter 2201 towards tissue track 36. The two clips 2204 and 2202 are then pulled toward each other until

20 tines 2208 of upper clip 2204 penetrate and lock into the receiving holes 2209 located in the lower clip 2202. Upon successful locking, the collapsible retaining unit 2207 is collapsed and both proximal and distal catheters are withdrawn leaving the clips behind as seen in FIG. 22a. The collapsible retaining unit may, for example, be a balloon, struts composed of shape memory material, or wire

25 pins controlled at the proximal end of the catheter.

A further welding device in accordance with an embodiment of the present invention is detailed in FIG. 23. Here a very similar scheme to that found in FIG. 8 is employed with the exception that energy is released from a central emitter core 2301 into the opposed openings of vessels 2 and 3. In this

30 case, after the two openings are opposed, by balloons 89 and 81, a central emitter core is advanced into the center of the catheter assembly 81 and 86 to a position

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directly at the midpoint of tissue track 36. Energy is emitted by this central emitter core to produce enough temperature in the local tissues surrounding the device to permit fusion. This energy and the emitter may be of the form of a 360 degree laterally firing laser fiber, microwave or other electromagnetic antennae, or locally mounted ultrasound producing piezoelectric crystal or laser emitter. Thermocouple 801 may also be helpful to define and control the welding process.

FIG. 12 depicts the final result after the coronary bypass procedure is complete. Normal coronary flow 34 is bypassed around stenosis 201 through tissue track 1202 into cardiac vein 3 and back into coronary artery 2 through tissue track 1203. Here a generic embolization device 1201 is shown blocking the upstream and downstream cardiac vein 3 in addition to a tributary vein 1204. In the case where simply cardiac venous arterialization is desired, only the proximal embolization and attachment would be required.

FIG. 13 depicts a generalized TVIS access port 1301. The TVIS port has a housing 130 and an entry port 138 which permits the introduction of various instruments. The entry port 138 may also have the ability to maintain pressure or hemostasis within the catheter alone or when instruments are inserted through it. Catheter 133 has a proximal portion which forms the housing 130 and a distal portion which forms the tip 1302. The TVIS access port 1301 may also be provided with an imageable marker 139 and a stabilizing balloon 134 located at its distal portion. After the TVIS guide catheter 5 shown in FIG. 5 obtains interstitial access and leaves behind a guidewire, the distal tip of the TVIS access port 1301 is placed percutaneously over the guidewire and advanced to the interstitial location 138. Upon identification of the marker 139 outside the vessel 132, the balloon 134 is inflated. Those skilled in the art should recognize that stabilization means at the tip may also include locking wires, expandable cages, and expandable stent-like frames. Once the TVIS access port is fixed in location, numerous other devices may be inserted for effecting a medical or therapeutic intervention. These include endoscopes 135, surgical tools 136 such as needles, cannula, catheter scissors, graspers, or biopsy devices, and energy delivery devices 137 such as laser fibers, bipolar and monopolar RF wires, microwave

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antennae, radiation delivery devices, and thermal delivery devices. Once one or more TVIS access ports 1301 are placed, various surgical procedures may be conducted completely through the vascular system on tissues in the periphery.

FIG. 14 shows another embodiment of a TVIS guide catheter 146 in accordance with the present invention. Here the TVIS guide catheter 146 is shown having an actively deflectable distal tip 145. In this case, the distal tip 145 is deflected by a shape memory material 142 embedded in the distal tip 145 of the device. When this material is heated by heating coil 147, the material rapidly bends into a desired configuration. A working channel 143 is provided for the advancement of the desired TVIS device. Here a needle 141 is shown infusing a drug 140 into the perivascular tissue. As discussed previously, the TVIS guide catheter 146 may also include a balloon 144 for stabilization within the vessel, and a passive imaging marker 148.

FIG. 15 depicts the same TVIS catheter 146 with the additional component of an active imaging device 23 as described previously. Also in FIG. 16, the TVIS probe 27 and TVIS sheath 26 are shown exiting the working channel 143 at the distal tip 145. Further, a flush channel 150 is also shown.

FIG. 17 depicts another method of creating an accurately sized tissue track 36 in accordance with an embodiment of the present invention. A retrograde tissue cutter catheter assembly 173 is advanced over guidewire 51 through tissue track 36. The retrograde tissue cutter assembly 173 has a cylindrical blade 171 attached to a dilating tip 170. The tip 170 is advanced through the tissue track 36 until the blade 171 is beyond the opening within artery 2. Once that position is found, a much larger base catheter 172 is advanced against the proximal opening within vein 3. The blade 171 and tip 170 are then pulled back against the edges of tissue track 36, capturing tissue within the cylindrical blade 171 as it is pressed against the base catheter 172. After the assembly 173 is removed, the resulting tissue track 36 is the size of the outer diameter of the cylindrical blade 171.

FIG. 18 depicts a TVIS guide catheter 182 in accordance with an embodiment of the present invention where a distal balloon 181 and a proximal balloon 180 isolate a section of the artery which is to be penetrated. This may be

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useful when using the TVIS guide catheter 182 in a high pressure vessel such as an artery. Such a catheter 182 may be used in a manner generally similar to the catheter 5 in FIG. 2.

Another alternative method in accordance with an embodiment of the present invention for bypassing a section of a vessel is depicted in FIGS. 19A and 19B. FIG. 19A depicts a TVIS guide catheter 146, such as described in FIGS. 14 and 15, but here having a distal tip 145 with an actively controlled shape memory material 142. Here the TVIS guide catheter 146 itself is shown tunneling through surrounding tissue utilizing probe 27 and sheath 26 to guide the way. Ultimately, the catheter 146 creates a tunnel 190 which can be used to allow flow from one point to another point in artery 2 as shown in FIG. 19B.

FIGS. 20, 20A and 20B depict the use of the device for transmyocardial revascularization in accordance with an embodiment of the present invention. FIG. 20 shows how the TVIS guide catheter 5 can be placed within the ventricle 2001 of the heart. The TVIS probe 27 is shown here creating an elongate channel 2003 through the heart muscle 2000. This channel may result in a direct communication between the ventricle and the small capillary vascular bed within the heart muscle 2000. FIG. 20A depicts how the alternative TVIS guide catheter 146 of FIG. 19A may be used to create these elongate channels 2003 within the heart. The TVIS guide catheter 146 is further modified in this case with a balloon tip 2002 for the purpose of covering the channel 2003 during vaporization; the balloon 2002 may be additionally assisted in assuring seating against the ventricle wall 2004 by providing a suction through the catheter 146 to an opening at the distal end of balloon 2002. Finally, FIG. 20B depicts TVIS guide catheter 5 creating several channels 2003 transvascularly, permitting blood flow from the vessel directly into the heart.

FIG. 24A depicts a side-to-side fistula stent 2400 in accordance with an embodiment of the present invention. The stent 2400 is fashioned like a clover with the leaves at alternating heights. The two top leaves 2401 and 2403 and the two bottom leaves 2402 and 2404 are placed such that they lie on either side of the vessel edge as shown in FIG. 24B. Intervening segments 2405 which are

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perpendicular to the planes of the clovers 2401 - 2404 lie within the channel created by the TVIS devices. The device is deployed from a catheter 2407 over a guidewire 2408 as shown in FIG. 24C. The stent is wrapped around an inner sheath 2409 such that clover leaves 2401 and 2403 are distal and 2402 and 2404 are proximal. As the catheter 2407 is moved relative to sheath 2409, the two distal clovers 2401 and 2403 are released, the device is withdrawn until the clovers 2401 and 2403 come in contact with inner surface of the distal vessel. Then the catheter 2407 is moved further with respect to the sheath 2409 and the proximal clovers 2402 and 2404 are released onto the inner surface of the proximal vessel as shown in FIG. 24 E.

FIG. 25 depicts more detail of the various types of devices which may be advanced through the TVIS catheter 146 in accordance with an embodiment of the present invention. Here, a wire 2501 is shown having advanced over it a dilator 2502 and a sheath 2503 through the vessel wall 2504.

Alternatively, a separate sheath such as the one shown in FIG. 13 can be advanced. FIGS. 26A and 26B show more detail on the components of such a system. Initially, the TVIS catheter is used to place a locking guidewire 2602 into the tissue. The guidewire has a very small locking tie 2604 which serves to anchor it in the tissue during device exchange. Then, over the locking guidewire 2602 the TVIS port introducer assembly shown in FIG. 26A is advanced. The assembly includes a dilator 2601 within a catheter 133. The catheter 133 is provided with a stabilization means 134 illustrated here as a balloon. After the catheter 133 is in place, and the stabilization means 134 is deployed, the dilator 2601 and the locking guidewire 2602 are removed. Depending on the situation, housing 1301 may or may not be equipped with a valve to prevent backflow into the catheter 133. Subsequently, various instruments may be inserted into the catheter 133 as described previously.

Another embodiment of the TVIS catheter in accordance with the present invention can be seen as item 2704 in FIGS. 27A and 27B. Here the TVIS catheter 2704 is made with a pre-formed curve seen in FIG. 27A. When the catheter is constrained as seen in FIG. 27B it can be held in a linear position. Guidewire

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2701 can be seen exiting the guidewire lumen 2709 when the catheter 2704 is held linearly (FIG. 27B) and can exit the side hole 2702 when the catheter is allowed to regain its preformed shape (FIG. 27A). A TVIS probe 2703 is shown entering another channel and exiting the device at the tip in either position. The catheter  
5 2704 can be used in the manner of other catheters discussed previously but has the benefit of being able to cause the tip to be curved in a desired direction.

A further embodiment of a TVIS catheter 2800 in accordance with the present invention is shown in FIG. 28. Here the two openings in the vessels are made with a vaporizing energy beam 2805 instead of a probe. This method  
10 utilizes an energy guide 2801, which beams energy at a deflecting plate 2802, which in turn sends the energy laterally into the tissue. The duration and energy level must be finely set to ensure that the opposite wall of vessel 2 is not damaged. Also shown in the diagram is the optional guidewire 2804, which may be used to block or signal the penetration of the laser energy.

15 FIG. 29 depicts another mechanism for widening or cutting the hole in accordance with an embodiment of the present invention. Here the device is advanced through the tissue channel over guidewire 2903, the cutting wings 2901 are expanded by moving sheath 2904 relative to central body 2902. The wings 2901 may be sharp, or the use of additional energy may be used to widen the  
20 hole as the device is withdrawn through the tissue channel.

FIGS. 16 and 21 are intentionally omitted.

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## Claims:

- 1 A method for effecting revascularization of a diseased artery comprising:
  - a) forming a first opening in a vein proximate to the diseased artery;
  - b) forming a second opening in the diseased artery in a location
  - 5 proximate to the first opening; and
  - c) providing a passage for the flow of blood between the first and second openings.
- 2 A method for effecting revascularization of a diseased artery in the heart
- 10 comprising:
  - a) forming a first opening in a blood vessel at a point within the circulatory system of the heart;
  - b) forming a second opening in a blood vessel at another position within the circulatory system of the heart; and
  - 15 c) providing for the passage of blood between the first and second openings.
- 3 A device for effecting tissues beyond the lumen of a blood vessel comprising:
  - 20 a) a catheter with proximal and distal ends, the distal end being adapted to pass into the vascular system to a desired surgical location, and the proximal end being adapted to remain outside of the body to allow for control by an operator;
  - b) orientation means provided on the distal portion of the catheter for
  - 25 allowing the operator to determine the axial rotational position of the catheter within the lumen; and
  - c) penetrating access means, provided on the distal portion of the catheter, for creating an opening and extending into the space beyond the lumen.
- 30 4. A device for routing blood from one blood vessel segment, through a tissue channel to second blood vessel segment comprising:

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- a) a tubular member having a proximal portion, a midsection portion and a distal portion;
  - b) the proximal portion capable of assuming the diameter of the first vessel;
  - 5 c) the midsection portion capable of assuming the diameter of the tissue channel; and
  - d) the distal portion capable of assuming the diameter of the second blood vessel.
- 10 5. A method of dilating a tissue channel formed between two blood vessels comprising:
- a) passing a guidewire through the tissue channel;
  - b) advancing a balloon with proximal and distal portions over the guidewire;
  - 15 c) locating the balloon so that the proximal and distal portions extend into the lumens of both blood vessels; and
  - d) inflating of the balloon.
6. A device for creating a widened space from a first blood vessel segment,
- 20 through a tissue channel, into a second blood vessel segment comprising:
- a) a catheter with a proximal end and a distal end for insertion into the vascular system; and
  - b) an energy guide whose exit is located at the distal end of the catheter and is capable of delivering energy into tissue to form a tissue channel from a
  - 25 portion of the vascular system.
7. A device to permit the attachment of a first opening in a first blood vessel to a second opening in a second blood vessel comprising:
- a) a first shaft with a proximal end and distal end;
  - b) a first expandable portion located on the first shaft, capable of being
  - 30 expanded within the first blood vessel;
  - c) a second shaft with a proximal and distal end;

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- d) a second expandable portion on the second shaft capable of being expanded within the second vessel;
  - e) means for bringing the two expanded portions towards each other to create first and second openings opposed to one another to permit flow between  
5 the first and second blood vessels.
8. A device for providing a one-way valve within a vessel comprising:
- a) a stent with a tubular shape and a proximal end and a distal end; and
  - b) a membrane provided within the stent capable of collapsing upon itself  
10 at the distal end of the stent while remaining the diameter of the stent at the proximal end.
9. A port for the purpose of providing transvascular interstitial access comprising:
- 15 a) a catheter with a proximal end and a distal end and at least one lumen;
  - b) the proximal portion of the catheter and having a housing to permit the introduction of various instruments into the catheter; and
  - c) the distal portion of the catheter adapted to be introduced through a blood vessel, through an opening in the wall of the blood vessel and into the  
20 interstitial space beyond the lumen of the blood vessel.
10. A device for enlarging a channel between a first opening in a first blood vessel and a second opening in a second blood vessel comprising:
- 25 a) a first and second shafts with proximal and distal portions;
  - b) a cylindrical blade located on the first shaft for cutting out a segment of tissue;
  - c) a receptacle for the cylindrical blade located on the second shaft; and
  - d) a means for bringing the cylindrical blade into contact with the  
30 receptacle.

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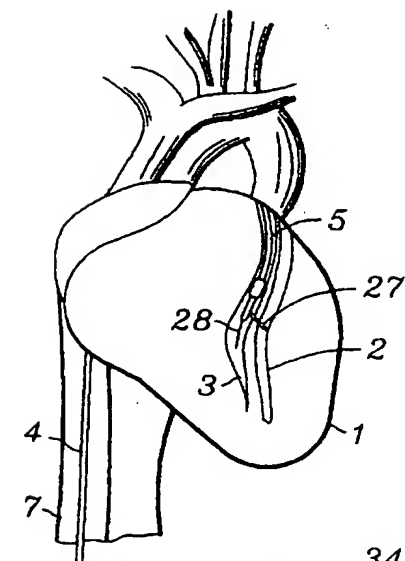


FIG. 1

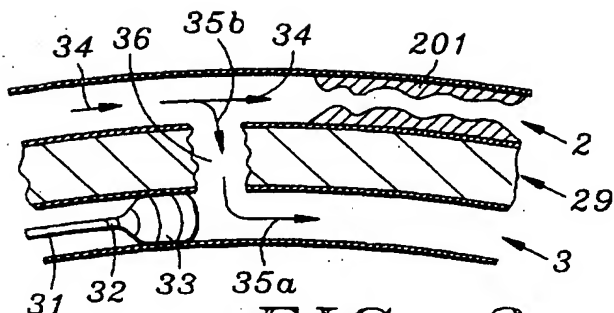


FIG. 3

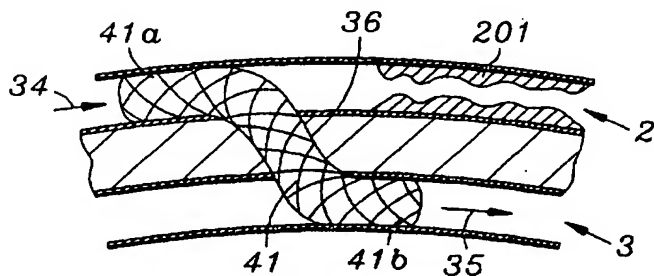


FIG. 4

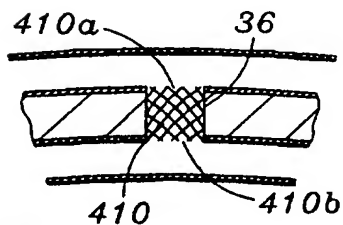


FIG. 4a

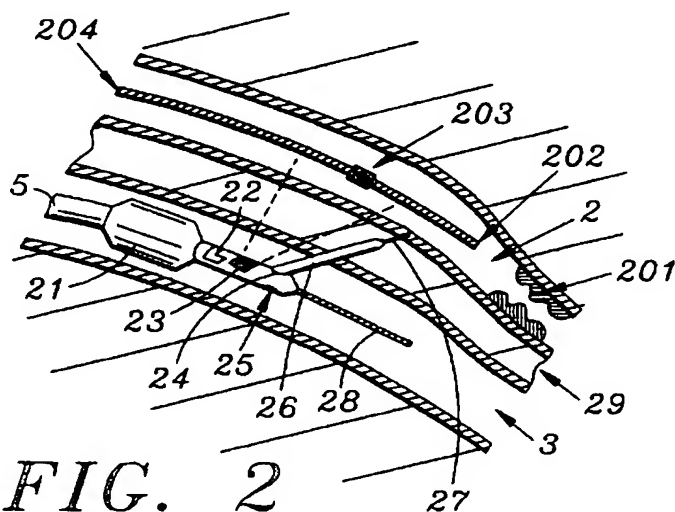
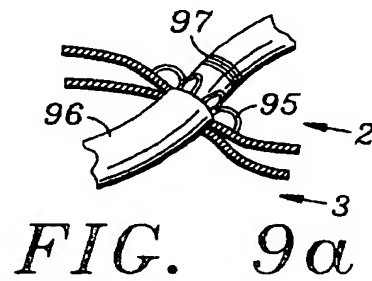
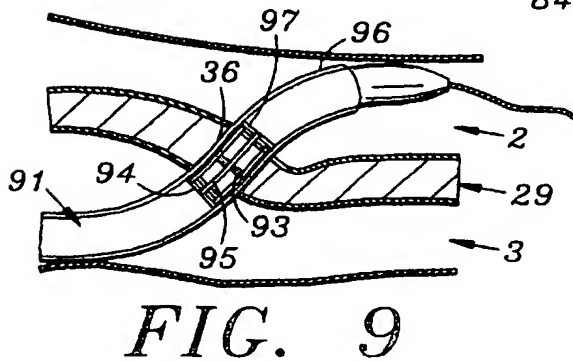
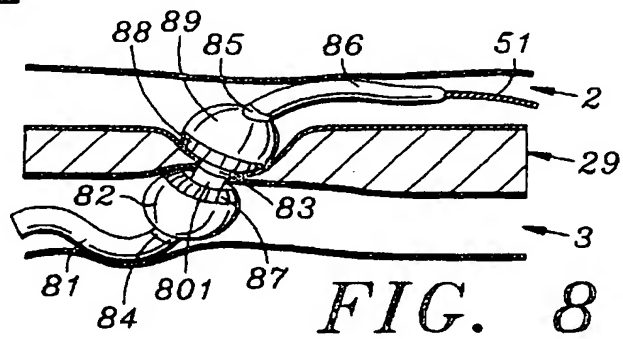
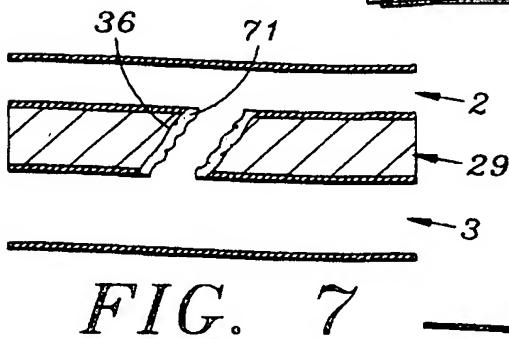
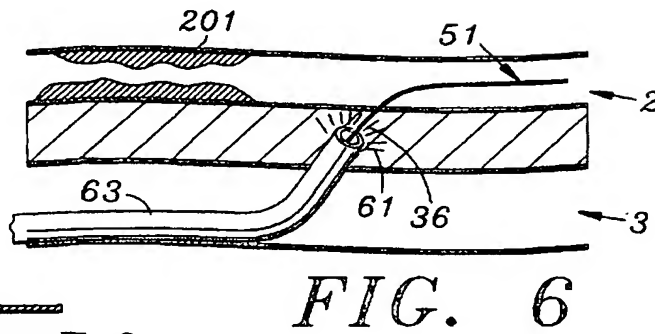
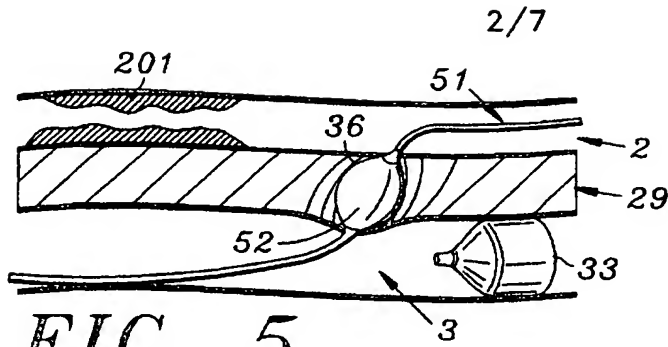


FIG. 2



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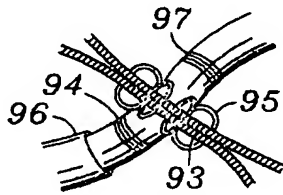


FIG. 9b

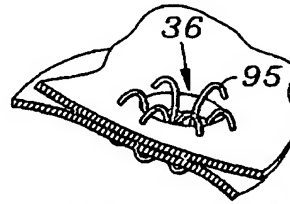


FIG. 9b

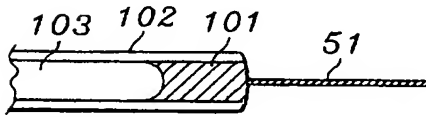


FIG. 10a

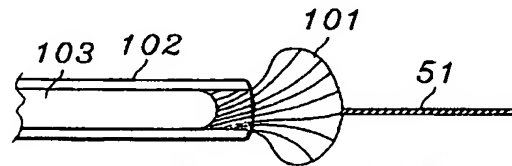


FIG. 10b

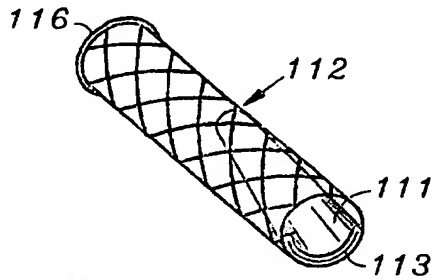


FIG. 11a

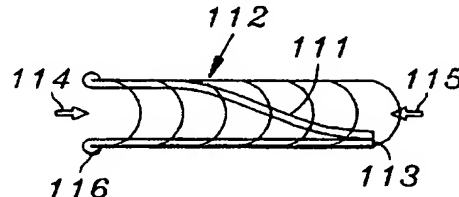


FIG. 11b

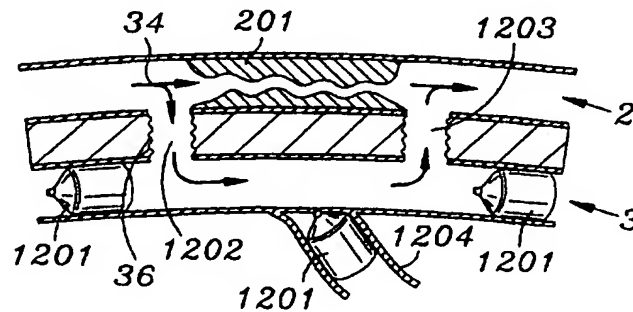


FIG. 12

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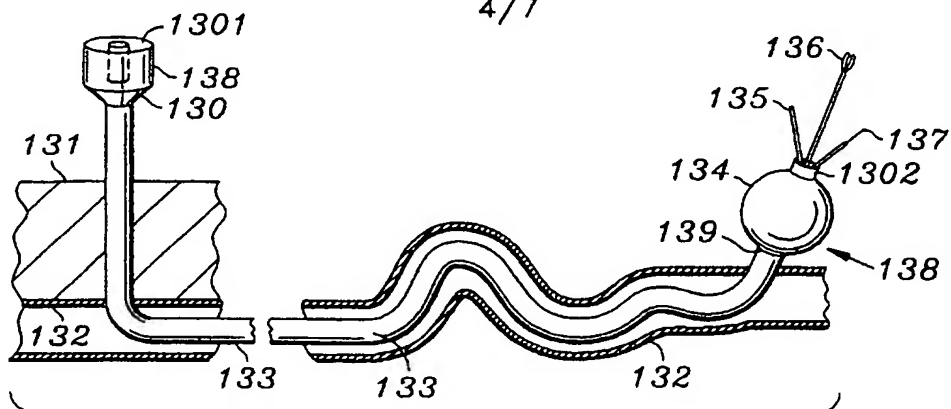


FIG. 13

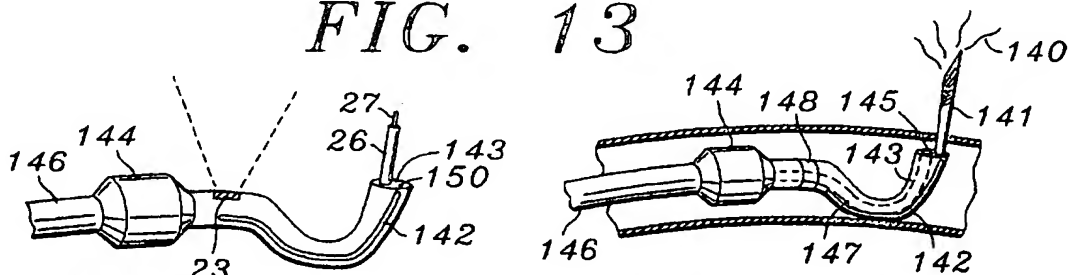


FIG. 15

FIG. 14

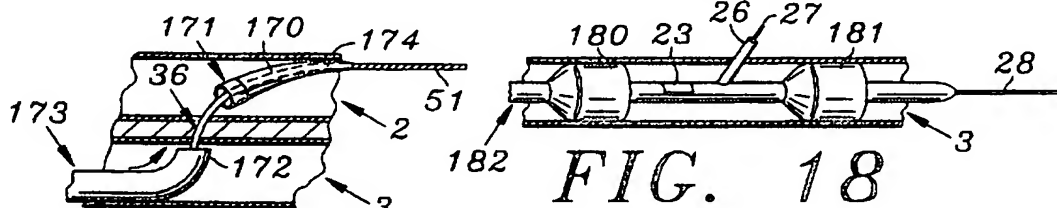


FIG. 17

FIG. 18

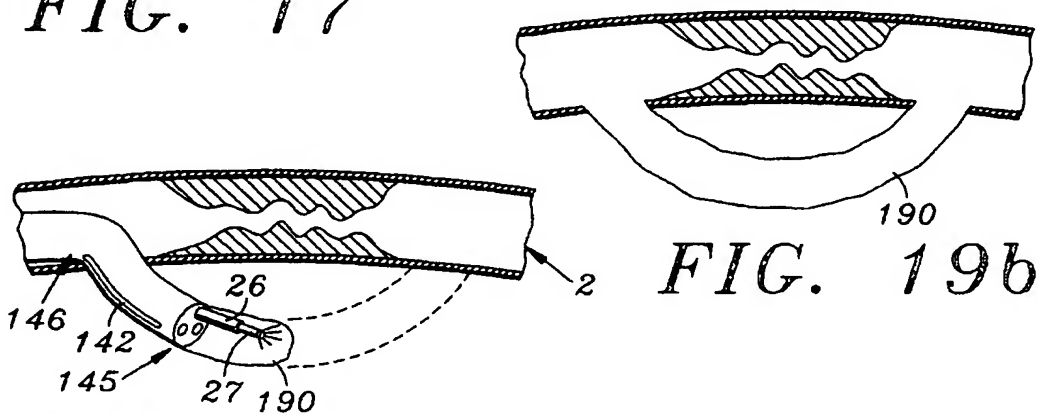


FIG. 19a

FIG. 19b

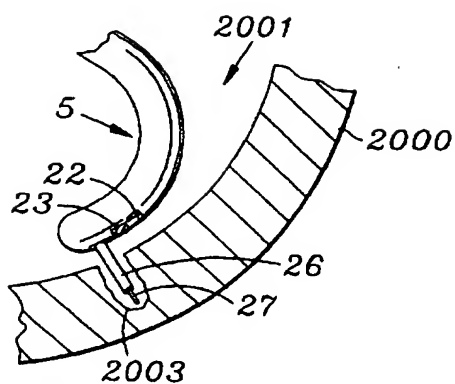


FIG. 20

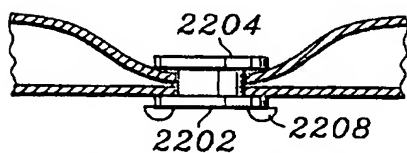


FIG. 22a

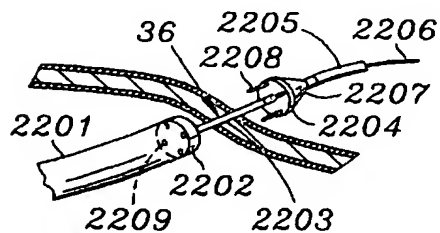


FIG. 22

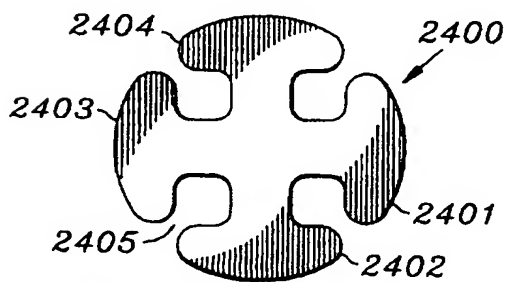


FIG. 24a

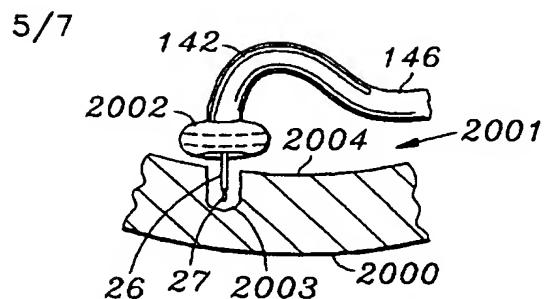


FIG. 20a

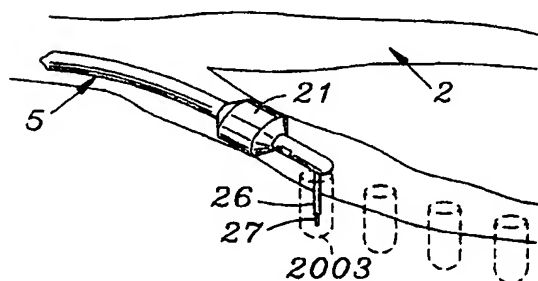


FIG. 20b

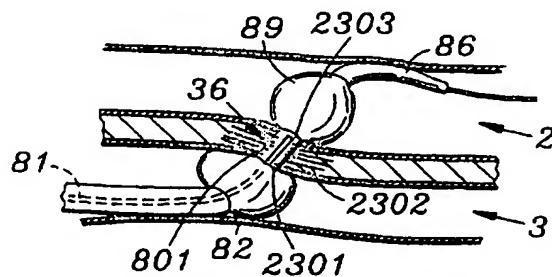


FIG. 23

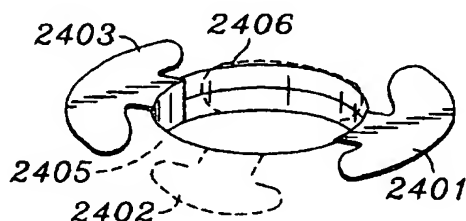


FIG. 24b

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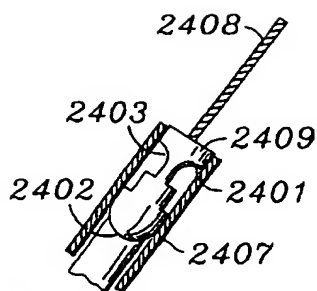


FIG. 24c

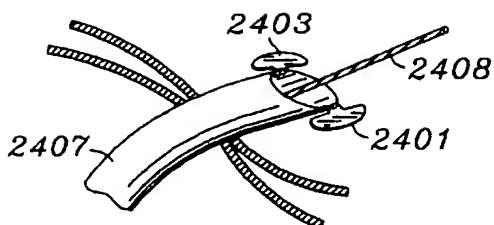


FIG. 24d

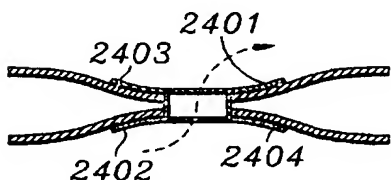


FIG. 24e

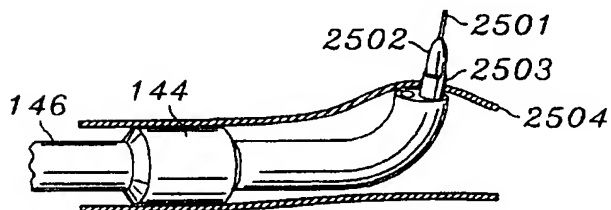


FIG. 25

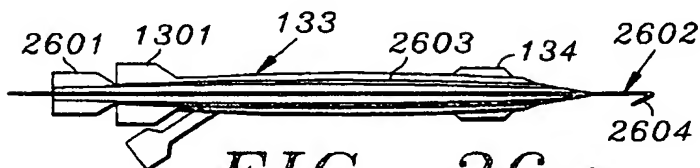


FIG. 26a



FIG. 26b

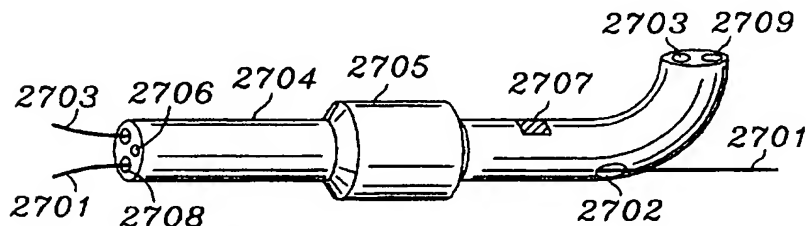
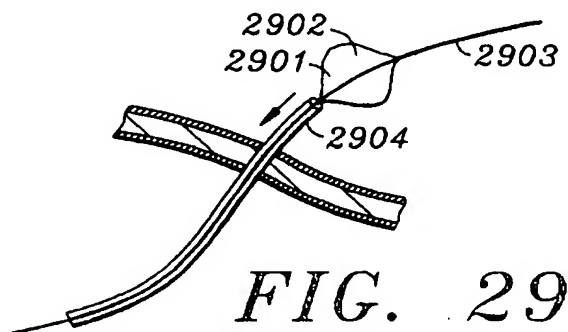
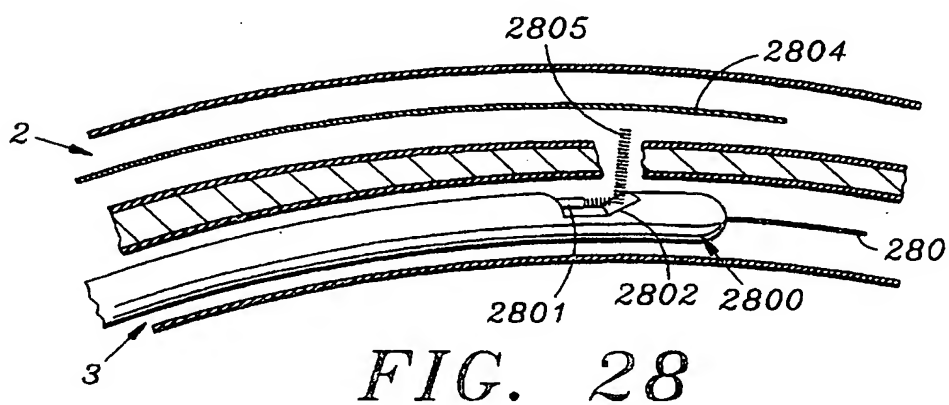
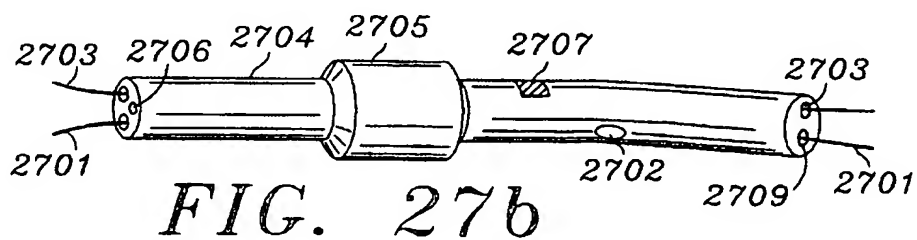


FIG. 27a

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## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US96/16268**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) :A61B 19/00

US CL :128/897

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/897; 604/008-010; 606/167-171, 191-199; 623/1, 12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,443,497 A (VENBRUX) 22 August 1995, entire document.	4, 7
A	US 2,935,068 A (DONALDSON) 03 May 1960, entire document.	1-10
A	US 3,156,408 A (MONTANTI) 23 June 1970, entire document.	1-10
X	US 5,290,294 A (COX et al) 01 March 1994, abstract, lines 7-15.	9

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Date of mailing of the international search report

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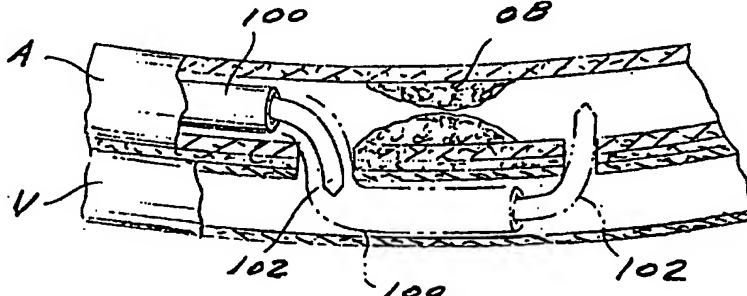
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345

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>A61B 17/00</b>		A1	(11) International Publication Number: <b>WO 97/13463</b>
			(43) International Publication Date: 17 April 1997 (17.04.97)
(21) International Application Number: <b>PCT/US96/16483</b>			(74) Agents: BUYAN, Robert, D. et al.; Stetina Brunda & Buyan, Suite 401, 24221 Calle de la Louisa, Laguna Hills, CA 92653 (US).
(22) International Filing Date: 11 October 1996 (11.10.96)			
(30) Priority Data: 60/005,164 13 October 1995 (13.10.95) US 60/010,614 2 February 1996 (02.02.96) US			(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).
(71) Applicant: TRANSVASCULAR, INC. [US/US]; 1505-D Adams Drive, Menlo Park, CA 94025 (US).			
(72) Inventors: MAKOWER, Joshua: 177 Yerba Buena Avenue, Los Altos, CA 94022 (US). FLAHERTY, J., C.; 766 La Prenda Road, Los Altos, CA 94024 (US). MACHOLD, Timothy, R.; 65 Bernal Avenue, Moss Beach, CA 94038 (US). WHITT, Jason, B.; 2616 Leavenworth Street, San Francisco, CA 94133 (US). EVARD, Philip, C.; 3192 Bryant Street, Palo Alto, CA 94306 (US). MACAULAY, Patrick, E.; 3268 Flintview Court, San Jose, CA 95148 (US). GARIBOTTO, John, T.; 6284 Lido Court, Newark, CA 94560 (US). VIDAL, Clade, A.; 5426 San Patricio Drive, Santa Barbara, CA 93111 (US). REDMOND, Russel, J.; 1148 North Fairview Avenue, Goleta, CA 93117 (US). BANKS, Thomas; 4002 Via Lucro, Santa Barbara, CA 93110 (US).			Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.
(54) Title: METHODS AND APPARATUS FOR BYPASSING ARTERIAL OBSTRUCTIONS AND/OR PERFORMING OTHER TRANSVASCULAR PROCEDURES			
(57) Abstract			
<p>This invention is methods, devices, and systems for re-vascularization, and/or performing other medical procedures at a vascular or non-vascular intra-corporeal locations within a mammalian body. The methods generally comprise the formation of at least one extravascular passageway from a blood vessel to a vascular or non-vascular target location. In the re-vascularization methods the extravascular passageway is utilized as a conduit for accessing or performing procedures at the vascular or non-vascular target location. Also disclosed are catheter devices (100, 103) and systems (138) which are usable to form the extravascular passageways of the invention, as well as apparatus for modifying, maintaining and/or closing such extravascular passageways.</p>			

\* (Referred to in PCT Gazette No. 32/1997, Section II)

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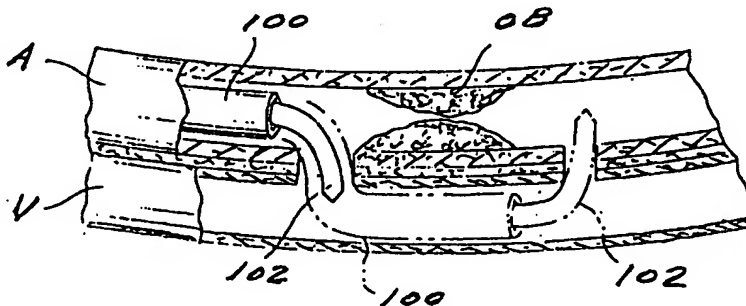
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(54) Title: METHODS AND APPARATUS FOR BYPASSING ARTERIAL OBSTRUCTIONS AND/OR PERFORMING OTHER TRANSVASCULAR PROCEDURES			
(57) Abstract			
<p>This invention is methods, devices, and systems for re-vascularization, and/or performing other medical procedures at a vascular or non-vascular intra-corporeal locations within a mammalian body. The methods generally comprise the formation of at least one extravascular passageway from a blood vessel to a vascular or non-vascular target location. In the re-vascularization methods the extravascular passageway is utilized as a conduit for accessing or performing procedures at the vascular or non-vascular target location. Also disclosed are catheter devices (100, 103) and systems (138) which are usable to form the extravascular passageways of the invention, as well as apparatus for modifying, maintaining and/or closing such extravascular passageways.</p>			



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**METHODS AND APPARATUS FOR BYPASSING ARTERIAL OBSTRUCTIONS  
AND/OR PERFORMING OTHER TRANSVASCULAR PROCEDURES**

**Related Applications**

5        This application claims priority to United States  
Provisional Applications Nos. 60/005,164 filed October  
13, 1995 and 60/010,614 filed February 2, 1996. The  
entire disclosures of Provisional Applications Nos.  
60/005,164 and 60/010,614 are expressly incorporated  
10       herein by reference.

**Field of the Invention**

      The present invention pertains generally to medical  
methods, devices, and systems, and more particularly to  
methods, devices, and systems for a) revascularization  
15       and/or b) performing medical procedures at vascular or  
non-vascular intracorporeal locations within a mammalian  
body.

**Background of the Invention**

**A. Background Relating to Revascularization Procedures**

20       In modern medical practice, it is often desirable to  
bypass segments of artery which have become obstructed,  
diseased or injured. The typical surgical procedures  
used for bypassing of obstructed, diseased or injured  
segments of blood vessel require open surgical exposure  
25       of the artery, and the attachment (e.g., suturing) of a  
tubular graft (e.g., homograft, xenograft, allograft,  
prosthetic or bioprosthetic graft) to the affected artery  
such that one end of the graft is connected upstream of  
the obstructed, diseased or injured segment, and the  
30       other end of the graft is connected to the artery  
downstream thereof. In this manner, arterial blood is  
channeled through the bypass graft, thereby restoring  
blood flow distal to the obstructed, diseased or injured  
segment of artery, and preventing tissue ischemia,  
35       infarction, and other sequelae which may result from  
impaired blood flow through the affected artery.

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Although surgical bypass grafting of arteries has been performed at various locations within the body, it is most typical for such arterial bypass procedures to be performed for the treatment of either i) coronary artery disease or ii) peripheral vascular disease affecting the lower extremities.

i. Coronary Artery Disease

Coronary artery disease continues to be one of the leading causes of morbidity and mortality, throughout the world. The typical etiology of coronary artery disease is characterized by the build-up of atherosclerotic plaque within the coronary arteries. Such deposits of atherosclerotic plaque tend to fully or partially block the flow of blood through the affected coronary arteries, and if untreated can result in myocardial ischemia, infarction and death.

For many years, the traditional surgical treatment of coronary artery disease has been coronary artery bypass surgery wherein the patient is generally anesthetized, placed on cardiopulmonary bypass and the patient's heart is temporarily stopped. A thoracotomy (e.g., a median sternotomy) is performed and the obstructed coronary blood vessels are exposed by surgical dissection. One or more segments of the patient's saphenous vein or internal mammary artery is/are harvested for use as bypass graft(s). The harvested segment(s) of vein or artery is/are then anastomosed to the obstructed coronary artery(ies) to form bypass conduit(s) around the arterial obstruction(s). Such traditional coronary artery bypass surgery is expensive, extremely invasive, and is associated with significant operative and preoperative complications.

One alternative to traditional coronary artery bypass surgery is balloon angioplasty. In balloon angioplasty, a flexible guide catheter is percutaneously inserted into a peripheral artery (e.g., the femoral artery) and is transluminally advanced through the

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vasculature until the distal tip of the catheter is within the ostium of an obstructed coronary artery. Thereafter, a balloon catheter is passed through the guide catheter and into the obstructive lesion. The balloon of the balloon catheter is inflated one or more times to dilate coronary artery in the region of the obstructive lesion. These balloon angioplasty procedures tend to be less expensive and less traumatic than traditional coronary artery bypass surgery. However, balloon angioplasty procedures of this type may be associated with a significant incidence of restenosis at the angioplasty site. The cause and mechanism of such restenosis continues to be the subject of ongoing study. However, such restenosis has generally been attributed to either a) an increase in the mass of the artery wall (e.g., neointima formation), b) a thickening of the artery wall without substantial change in it's mass (e.g., vascular remodeling) and/or c) radial contraction of the balloon-dilated artery wall upon healing of cracks and fissures that have been created by the balloon dilation process.

Another alternative to traditional coronary artery bypass surgery is intraluminal removal (e.g., atherectomy) or ablation (e.g., ultrasound, laser) of the obstructive matter within the coronary artery. These intraluminal removal or ablation procedures are performed by passing a catheter-mounted removal or ablation apparatus through the vasculature to the site of the coronary obstruction. The catheter-mounted removal or ablation apparatus is then utilized to cut, shave, sonicate, pulverize, or vaporize or otherwise ablate the obstructive matter from the lumen of the coronary artery. These procedures must be performed with caution to avoid perforation or damage to the artery wall, as such perforation or damage can result in hemorrhage or excessive scarring and subsequent reocclusion of the artery lumen. Furthermore, these ablative procedures

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may, in some cases at least, be confounded by the need to meticulously contain and remove dislodged or severed fragments of the obstructive matter, in order to prevent such fragments of obstructive matter from escaping into the patient's circulatory system. Examples of atherectomy catheters and other catheter-mounted ablative apparatus are described in United States Patent Nos. 3,433,226 (Boyd), 3,823,717 (Pohlman, et al.), 4,808,153 (Parisi), 4,936,281 (Stasz), 3,565,062 (Kuris), 4,924,863 (Sterzer), 4,870,953 (Don Michael, et al.), 5,069,664 (Suess, et al.), 4,920,954 (Alliger, et al.) and 5,100,423 (Fearnot), as well as foreign patents/patent publications EP0347098A2 (Shiber), WO87-05739 (Cooper), WO89-06515 (Bernstein, et al.), WO90-0130 (Sonic Needle Corp.), EP316789 (Don Michael, et al.), DE 3,821,836 (Schubert), DE2438648 (Pohlman), and EP 0443256A1 (Baruch).

Other alternatives to traditional coronary artery bypass surgery have included minimally invasive endoscopic procedures which may, ostensibly at least, be performed through small (e.g., 1-3cm) incisions formed in the patient's chest wall, by insertion of a thoracoscope and associated operative instruments through such incisions. One such minimally invasive coronary bypass procedure is described in United States Patent No. 5,452,733 (Stermann et al.). If perfected, these minimally invasive coronary artery bypass procedures may lessen the discomfort and length of recovery time experienced by patients who undergo such minimally invasive procedures vis a vis those who undergo traditional coronary artery bypass surgery. However, endoscopic surgical procedures of this type typically require a great deal of operator skill and training. Furthermore, as with traditional coronary artery bypass surgery, these thoracoscopic procedures are typically performed under general anesthesia, and typically require that one or more chest tubes be left in place during the

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postoperative period to drain any blood which leaks from the graft anastomoses and to reduce the pneumothorax which has been created by the formation of full-thickness incision(s) in the chest wall. Moreover, some of these thoracoscopic coronary artery bypass procedures require that the patient be placed on cardiopulmonary bypass, and that the patient's heart be temporarily stopped. Others of these thoracoscopic procedures purport to be useable without placing the patient on cardiopulmonary bypass, and without stopping the heart. However, those thoracoscopic procedures which purport to be useable without cardiopulmonary bypass and heart stoppage are relatively complex to perform and typically require temporary clamping or ligating of the coronary artery which is to be bypassed. Accordingly, even those thoracoscopic procedures which may be useable without cardiopulmonary bypass/heart stoppage are prone to unique and significant risks and difficulties due to the complexities of the procedure and the need for temporary clamping or closing off the coronary artery(s) being bypassed. Thus, many of the drawbacks associated with traditional coronary artery bypass surgery, as well as additional potential drawbacks, may be associated with these minimally invasive thoracoscopic procedures.

Another previously described procedure which does not actually bypass coronary artery obstructions but which nonetheless may be useable to improve blood flow to ischemic regions of the myocardium, is a procedure known as transmyocardial revascularization (TMR). In the TMR procedure a tissue-penetrable probe, such as a laser probe, is utilized to form numerous full-thickness penetrations through the ischemic myocardial wall, and into the chamber of the left ventricle. Oxygenated blood from the left ventricle then flows outwardly through such penetration tracts, so as to perfuse the ischemic myocardium. Examples of such transmyocardial revascularization procedures are described in United

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States Patent Nos. 5,554,152 (Aita et al.), 5,380,316 (Aita et al.), and 5,125,926 (Linhares et al.)

One modification of the TMR procedure requires the formation of a valved and/or internally stented transmyocardial passageway (e.g., an interstitial tunnel formed in the muscular wall of the heart) from the left ventricle of the heart to an obstructed coronary artery, downstream of the obstruction. Such modified TMR procedure, is described in United States Patent Nos. 5,287,861 (Wilk), 5,409,019 (Wilk), and 5,429,114 (Wilk).

ii. Peripheral Vascular Disease

Peripheral vascular disease commonly results from the build up of atherosclerotic plaque and/or thrombotic matter within peripheral arteries. In many cases, when arteries of the lower extremities have become obstructed by peripheral vascular disease, a phenomenon known as intermittent claudication results. Intermittent claudication is characterized by the occurrence of pain and progressive weakness in the legs during exertion (i.e., walking or running).

The typical surgical approach to the treatment of peripheral vascular disease, especially in patients who exhibit symptoms of intermittent claudication, is to surgically expose the affected artery and to anastomose a tubular bypass graft (e.g., a tube of woven polyester or expanded polytetrafluoroethylene (ePTFE)) to the affected artery such that one end of the graft is attached upstream of the obstruction, and the other end of the graft is attached downstream of the obstruction. In this manner, arterial blood will flow through the tubular bypass graft and around the arterial obstruction, thereby restoring blood flow to the portion of the artery downstream of the obstruction.

One alternative to traditional arterial bypass graft surgery for the treatment of peripheral vascular disease of the lower extremities, is a procedure known as in situ vein bypass. These in situ vein bypass procedures are

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typically carried out by forming at least two (2) open incisions in the leg, to expose the affected artery at sites upstream and downstream of the obstruction. A peripheral vein, which extends through the leg generally parallel to the affected artery, is then prepared by inserting an instrument into the vein to lyse or disrupt the venous valves located within the vein. Thereafter, any side branches which extend from the vein are cut, ligated or blocked by embolization. The prepared vein is then transected at locations above and below the arterial obstruction, and the transected ends of the vein are placed in contact with, and sutured directly to, the artery at sites upstream and downstream of the obstruction. In this manner, arterial blood flow becomes channeled through the prepared segment of vein, such that the prepared segment of vein will act as bypass conduit around the arterial obstruction. Examples of current in situ vein bypass procedures are described in White, R.A. and Fogarty, T.J., Peripheral Endovascular Interventions, Pgs., 166-169, Mosby & Co. (1996).

**iii. Trauma and Other Diseases Which May Impair Flow Through Arteries**

Various arteries of the body may become damaged by trauma (e.g., lacerations, crushing injury, blunt abdominal trauma) or may become invaded or compressed by extra-vascular disease processes (e.g., to proliferation and ingrowth of an adjacent tumor). The typical surgical approach to treatment of arteries affected by such trauma or disease is to surgically expose and direct the affected segment of artery, and to thereafter a) resect and reconnect or b) bypass the affected segment of artery, to restore arterial blood flow through or around the affected segment of the artery. In many such cases, the segment of artery affected by the injury or disease may be so large as to preclude simple resection, removal of the affected segment, and end-to-end anastomosis of the adjacent cut ends of the artery. Accordingly, in

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such instances where resection and end-to-end anastomosis is not an available option, it may be desirable to attach a tubular bypass graft (e.g., a tubular graft formed of woven polyester, or ePTFE) to the affected artery, to  
5 bypass the affected segment of the artery.

Although a number of the above-described surgical procedures represent relatively recent advancements whereby the invasiveness and risk associated with traditional surgical approaches have been mitigated,  
10 there remains a need in the art for the development of new, safe, and reliable minimally invasive and/or transluminal procedures for bypassing segments of arteries which have become obstructed, injured or affected by disease.

15 **B. Background Relating to Other Extravascular Surgical/Interventional Procedures**

Many types of surgical and interventional procedures have previously been formed in organs, tissues or body cavities of the body. Traditionally, access to such  
20 organs, tissues or body cavities is attained through the formation of one or more open surgical incisions in the body, whereby the affected organs, tissues or body cavities are surgically exposed.

In recent years, substantial efforts have been undertaken to develop "minimally invasive" surgical techniques whereby one or more endoscopes are utilized to view the affected organ, tissue or body cavity, operative instruments or other devices are inserted into the body to accomplish the desired surgical or interventional  
30 procedure through relatively small, "minimal access" (e.g., less than 3cm) incisions.

Although the advent of these endoscopic "minimal access" surgical procedures may have advantageous over traditional open surgical techniques insofar as they may  
35 minimize the size of the surgical incision, and accordingly, may lead to less post-operative discomfort, such endoscopic procedures are often limited to

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procedures within accessible body lumens or cavities which may be filled with clear liquid or insufflated with a gas to provide an open area within which to place the operative endoscope(s) and instrument(s).

5 In view of the limitations associated with the even the most modern "minimal access" surgical and interventional procedures, there remains a need in the art for the development of new methods and apparatus for accessing tumors, organs, tissues and other extravascular  
10 locations within the body, to permit the performance of surgical and/or interventional procedures without the need for forming any open surgical incisions in the body.

#### Summary of the Invention

In general, the present invention provides methods  
15 for using the vascular system of a mammalian body as a conduit for performing various types of medical procedures. Due to the wide distribution of vessel conduits throughout the body, the vascular system provides a highway through which devices can be navigated  
20 to reach selected treatment sites which may be otherwise only accessible through a direct incision. The specific methods of the present invention include a) revascularization methods, and b) methods for performing various types of medical procedures at extravascular  
25 locations within the body.

The revascularization methods of the present invention generally comprise the formation of one or more extravascular passageways between blood vessels, different locations on the same blood vessel, or a blood  
30 vessel and another blood-containing anatomical structure (e.g., chamber of the heart), such that blood will flow through such passageway(s). In many applications of the invention, it will be desirable for oxygenated blood (i.e., blood which has a  $pO_2$  greater than 50) to be  
35 carried through the extravascular passageway(s) for the purpose of providing or enhancing perfusion of tissues. The extravascular passageways formed in accordance with

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the revascularization methods of the present invention may be formed by a percutaneous, transluminal approach which avoids the formation of open surgical incisions in the mammalian body. These revascularization methods of the present invention may be useable in peripheral blood vessels and/or in coronary blood vessels.

In accordance with the revascularization methods of the present invention, there are provided procedures for providing arterial blood flow to a tissue which has been deprived of blood due to the presence of an obstruction, injury or disease within a segment of an artery. The method generally comprises the step of forming a first extravascular passageway between an anatomical conduit which contains arterial blood (e.g., an artery or chamber of the left heart), and a blood vessel which will perfuse the blood-deprived tissue, such arterial blood will pass through the extravascular blood flow passageway and into the blood vessel, so as to perfuse the blood-deprived tissue through the blood vessel. In some applications of this method, the first blood flow passageway will be formed between an artery and an adjacent vein, such that blood will flow from the artery into the adjacent vein and will subsequently pass through the vein in the retrograde direction so as to back-perfuse tissue through the venous vasculature. Alternatively, a second blood flow passageway may be formed between the vein and the artery wherein the obstruction, injury or disease is located, such that arterial blood which has entered the vein will reenter the artery, downstream of the obstruction, injury or disease-affected segment thereof, thereby perfusing the blood-deprived tissue through the endogenous artery wherein the obstruction, injury or disease-affected segment is located. The medical procedure methods of the present invention broadly comprise the step of forming at least one extravascular passageway from a blood vessel to another intracorporeal location (eg., blood vessel, organ, body cavity, tumor,

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etc.) and subsequently passing a substance or apparatus through the extravascular passageway to perform the desired medical procedure at the selected intracorporeal location.

5 Further in accordance with the invention, there is provided a device which is insertable into a blood vessel and useable to form an extravascular passageway which extends from the blood vessel within which the catheter device is inserted to a target location (e.g., a) another  
10 blood vessel, b) another blood containing anatomical structure (e.g., chamber of the heart), c) another location on the same blood vessel, or d) an extravascular location. (e.g., organ, tumor, body cavity, etc.)) Extravascular passageways formed by this catheter device  
15 may be used for performance of the methods of the present invention, as summarized hereabove. This passageway-forming catheter device may comprise an elongate, flexible catheter body having a tissue penetrating element (e.g., a member, device or flow of energy) which  
20 is passable from the catheter body, to form a passageway through the wall of the blood vessel in which the catheter is positioned, and through any other tissue located between the blood vessel and the target location (e.g., other blood vessel, anatomical structure,  
25 extravascular location, or other location on the same blood vessel) to which the passageway is desired to extend. The tissue-penetrating element may comprise a suitable type of tissue-penetrating member, device or flow of energy, including but not necessarily limited to  
30 hollow and/or solid needle, trocar-tipped needle (with or without a surrounding pliable sheath), laser beam, laser-emitting member, electrocautery probe, hot-tipped probe, rotating tissue penetrating apparatus, or ultrasonic ablation probe. Optionally, the catheter device may be  
35 equipped with suction lumen, inflatable balloon(s) or other structural attributes or apparatus useable to facilitate or assist the passage of the tissue-

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penetrating element (e.g., member, apparatus, flow of energy) from the blood vessel to the selected target location. Also, optionally, the tissue-penetrating element of the catheter device may incorporate a guide  
5 wire lumen or other means for passing a guide wire through the extravascular passageway formed by the tissue-penetrating element.

Further in accordance with the invention, the passageway-forming catheter device of the foregoing  
10 character may be combined with one or more apparatus for orienting the tissue-penetrating element to insure that the extravascular passageway is formed at its intended location. Such orienting apparatus may be mounted upon or incorporated into the passageway-forming catheter, or  
15 may be formed separately of the passageway-creating catheter and used in conjunction with the catheter, from any suitable intracorporeal and/or extracorporeal location. The orienting apparatus may comprise various types of active and/or passive apparatus including, but  
20 not limited to, extracorporeal or intracorporeal ultrasound apparatus, extracorporeal or intracorporeal Doppler apparatus, intracorporeal or extracorporeal radiographic apparatus, magnetic resonance imaging apparatus, tomography apparatus, induction coils,  
25 electromagnetic devices, and various catheter-borne markers which are identifiable by radiographic, sonic, ultrasonic, photographic, MRI, or other means.

Still further in accordance with the invention, there are provided passageway-modifying devices for  
30 debulking, lining, stenting, longitudinally compressing and/or otherwise modifying the extravascular passageway(s) which are formed by the present invention.

Further objects and advantages of the present invention will become apparent to those skilled in the  
35 art upon reading the detailed description of preferred embodiments set forth herebelow, wherein certain

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presently-preferred embodiments and examples of the invention are set forth in detail.

**Brief Description of the Drawings**

Figure 1a is a front perspective view of a human heart showing the typical locations of coronary arteries and veins thereon.

Figure 1b is a rear perspective view of the human heart showing the typical positions of arteries and veins thereon.

Figure 1c is a longitudinal sectional view through an adjacent coronary artery and coronary vein within segment 1c of Figure 1a, wherein blood flow passageways have been formed in accordance with the present invention to bypass an obstruction located within the coronary artery.

Figure 1d is a cross sectional view through line 1d-1d of Figure 1c.

Figure 1e is a diagram of the Triangle of Brouck-Moscheau, an anatomical landmark which is defined by certain coronary arteries and coronary veins of the human heart, as visualized on an x-ray taken from the right anterior oblique view.

Figure 1f is a perspective view of an alternative revascularization method of the present invention wherein an extravascular interstitial passageway is formed from a first location on a blood vessel (upstream of an obstruction) to a second location on the same blood vessel (downstream of the obstruction).

Figure 1f' is a perspective view of the blood vessel shown in Figure 1f, following complete application of the revascularization method of the present invention to form a bypass passageway around the obstruction.

Figure 2 is a perspective view of a human body incorporating a schematic illustration of a transvascular method for performing a medical procedure at an extravascular location within the body, in accordance with the present invention.

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Figure 2a is an enlarged perspective view of the target tissue of Figure 2, showing the manner in which a tissue-penetrating element is passed from the passageway-forming catheter into the target tissue.

5        Figure 2a' is an enlarged view of the target tissue of Figure 2 showing an access conduit which has been advanced through and/or exchanged into the extravascular passageway into the target tissue.

10       Figure 2b is a schematic showing of an indwelling delivery/sampling cannula having a subcutaneous injection port for repetitive infusion/withdrawal of matter into/from or monitoring of conditions in the target area.

15       Figure 2c is a schematic showing of a catheter inserted through the extravascular passageway for temporarily deployment of a device into, monitoring of conditions in, or infusion/withdrawal of matter into/from the target area.

20       Figure 2d is a schematic showing of a permanently placed device (e.g., fluid drainage shunt) utilizing the extravascular passageway of the present invention.

25       Figure 2e is a schematic showing of a catheter inserted through the extravascular passageway of the present invention and into the lumen of another tubular anatomical passageway, for sampling, access, monitoring, or performance of a surgical or interventional procedure within the tubular anatomical passageway.

Figure 2f is a schematic showing of a transvascular procedure for performing extravascular microsurgery, in accordance with the present invention.

30       Figure 3a is a longitudinal sectional view showing an unmodified blood flow passageway formed in accordance with the present invention.

35       Figure 3b is a longitudinal sectional view showing an internally lined blood flow passageway formed in accordance with the present invention.

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Figure 3c is a longitudinal sectional view showing a longitudinally compressed blood flow passageway formed in accordance with the present invention.

Figure 3d is a longitudinal sectional view showing a blood flow passageway of the present invention having a non-protrusive stent or stented graft positioned therewithin.

Figure 3d' is a perspective view showing an optional flange and/or optional projections which may be incorporated into a non-protrusive stent or stented graft positionable within a blood flow passageway of the present invention in accordance with Figure 2d.

Figure 3e is a sectional view through a blood flow passageway of the present invention, having a first embodiment of a hemiprotrusive or protrusive stent or stented graft positioned therewithin.

Figure 3f is a sectional view through first and second blood flow passageways of the present invention, having a second embodiment of a protrusive stent or stented graft positioned therewithin.

Figure 4a is a schematic illustration of a first approach for forming arteriovenous blood flow passageways in accordance with the present invention.

Figure 4b is a schematic illustration of a second approach for forming arteriovenous blood flow passageways in accordance with the present invention.

Figure 4c is a schematic illustration of a third approach for forming arteriovenous blood flow passageways in accordance with the present invention.

Figure 4d is a schematic illustration of a fourth approach for forming arteriovenous blood flow passageways in accordance with the present invention.

Figure 4e is a schematic illustration of a fifth approach for forming an arteriovenous blood flow passageway in accordance with the present invention.

Figure 5a is a longitudinal sectional view of two (2) adjacent blood vessels, illustrating a first means

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for orienting, aiming and guiding a tissue-penetrating element to form an arteriovenous blood flow passageway in accordance with the present invention.

Figure 5b is a longitudinal sectional view of an adjacent artery and vein, illustrating a second means for orienting, aiming and guiding a tissue-penetrating element to form an arteriovenous blood flow passageway in accordance with the present invention.

Figure 5c is a longitudinal sectional view of an adjacent artery and vein, illustrating a third means for orienting, aiming and guiding a tissue-penetrating element to form an arteriovenous blood flow passageway in accordance with the present invention.

Figure 5d is a longitudinal sectional view of an adjacent artery and vein, illustrating a fourth means for orienting, aiming and guiding a tissue-penetrating element to form an arteriovenous blood flow passageway in accordance with the present invention.

Figure 5e is schematic showing of a method for utilizing passive radiographically visible markers to orient, aim and or guide a tissue-penetrating element to form an extravascular passageway in accordance with the present invention.

Figure 5e' shows a first type of radiographic markers which may be utilized in accordance with Figure 5e.

Figure 5e'' shows a second type of radiographic markers which may be utilized in accordance with Figure 5e.

Figure 5e''' shows a third type of radiographic markers which may be utilized in accordance with Figure 5e. Figure 5f is a schematic showing of a method for utilizing an ultrasonically visible marker to aim, align and/or guide a tissue penetrating element to form an extravascular passageway in accordance with the present invention.

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Figure 5f' is a perspective view of the ultrasonically visible marker shown in figure 5f.

Figure 5g is a schematic view of a method for using MRI to orient, aim or guide a tissue-penetrating element to form an extravascular passageway in accordance with the present invention.

Figure 5g' is a perspective view of a first embodiment of a marker visible by magnetic resonance imaging (MRI) to facilitate orientation, aiming and/or guidance of a tissue penetrating element to form an extravascular passageway in accordance with the present invention.

Figure 5g'' is a perspective view of a second embodiment of a marker visible by magnetic resonance imaging (MRI) to facilitate orientation, aiming and/or guidance of a tissue penetrating element to form an extravascular passageway in accordance with the present invention.

Figure 5h is a schematic showing of means for utilizing a doppler apparatus to facilitate orientation, aiming and/or guidance of a tissue penetrating element to form an extravascular passageway in accordance with the present invention.

Figure 5i is a schematic showing of means for a pressure sensing apparatus to facilitate orientation, aiming and/or guidance of a tissue penetrating element to form an extravascular passageway in accordance with the present invention.

Figure 5j is a schematic showing of means for utilizing transmitter and receiver apparatus for orienting, aiming and/or guiding a tissue penetrating element to form an arteriovenous blood flow passageway in accordance with the present invention.

Figure 5k is a schematic showing of means for utilizing transmitting and induction coil apparatus for orienting, aiming and/or guiding a tissue penetrating

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element to form an arteriovenous blood flow passageway in accordance with the present invention.

Figure 51 is a schematic showing of means for utilizing magnetic apparatus for orienting, aiming and/or  
5 guiding a tissue penetrating element to form an arteriovenous blood flow passageway in accordance with the present invention.

Figure 6a is a longitudinal sectional view of a portion of a transvascular tissue-penetrating catheter of  
10 the present invention, showing a first means for exiting of the tissue-penetrating element from the catheter.

Figure 6b is a longitudinal sectional view of a portion of a transvascular tissue-penetrating catheter of the present invention, showing a second means for exiting  
15 of the tissue-penetrating element from the catheter.

Figure 6c is a longitudinal sectional view of a portion of a transvascular tissue-penetrating catheter of the present invention, showing a third means for exiting of the tissue-penetrating element from the catheter.

Figure 6d is a longitudinal sectional view of a portion of a transvascular tissue-penetrating catheter of the present invention, showing a fourth means for exiting  
20 of the tissue-penetrating element from the catheter.

Figure 6d' is a perspective view through of the distal end of the catheter device shown in Figure 6d.  
25

Figure 6e is a longitudinal sectional view of a portion of a transvascular tissue-penetrating catheter of the present invention, showing a fifth means for exiting of the tissue-penetrating element from the catheter.

Figure 6f is a longitudinal sectional view of a portion of a transvascular tissue-penetrating catheter of the present invention, showing a sixth means for exiting  
30 of the tissue-penetrating element from the catheter.

Figure 6g is a longitudinal sectional view of a portion of a transvascular tissue-penetrating catheter of  
35 the present invention, showing a seventh means for

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exiting of the tissue-penetrating element from the catheter.

Figure 6h is a longitudinal sectional view of a portion of a transvascular tissue-penetrating catheter of the present invention, showing a eighth means for exiting  
5 of the tissue-penetrating element from the catheter.

Figure 6i is a longitudinal sectional view of a portion of a transvascular tissue-penetrating catheter of the present invention, showing a ninth means for exiting  
10 of the tissue-penetrating element from the catheter.

Figure 7a is a longitudinal sectional view of a distal portion of the first embodiment of a tissue-penetrating element in accordance with the present invention.

Figure 7a' is a cross sectional view through line 7a'-7a' of Figure 7a.  
15

Figure 7b is a longitudinal sectional view of a distal portion of the second embodiment of a tissue-penetrating element in accordance with the present  
20 invention.

Figure 7c is a longitudinal sectional view of a distal portion of the third embodiment of a tissue-penetrating element in accordance with the present invention.

Figure 7d is a longitudinal sectional view of a distal portion of the fourth embodiment of a tissue-penetrating element in accordance with the present  
25 invention.

Figure 7d' is a cross sectional view through line 7d'-7d' of Figure 7d.  
30

Figure 7e is a longitudinal sectional view of a distal portion of the fifth embodiment of a tissue-penetrating element in accordance with the present invention.

Figure 7e' is a cross sectional view through line 7e'-7e' of Figure 7e.  
35

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Figure 7e'' is cross sectional view through an alternative embodiment of the device shown in Figure 7e, comprising a hollow tube having a solid stylet positioned therewithin.

5        Figure 7f is a longitudinal sectional view of a distal portion of the sixth embodiment of a tissue-penetrating element in accordance with the present invention.

10       Figure 7f' is a perspective view of the trocar-tipped, elongate member which forms a portion of the tissue-penetrating element shown in figure 7f.

15       Figure 7g is a longitudinal sectional view of a distal portion of the seventh embodiment of a tissue-penetrating element in accordance with the present invention.

      Figure 7h is a longitudinal sectional view of a distal portion of the eighth embodiment of a tissue-penetrating element in accordance with the present invention.

20       Figure 7i is a longitudinal sectional view of a distal portion of the ninth embodiment of a tissue-penetrating element in accordance with the present invention.

25       Figure 7j is a longitudinal sectional view of a distal portion of the tenth embodiment of a tissue-penetrating element in accordance with the present invention.

30       Figure 7k is a longitudinal sectional view of a distal portion of the eleventh embodiment of a tissue-penetrating element in accordance with the present invention.

35       Figure 7l is a longitudinal sectional view of a distal portion of the twelfth embodiment of a tissue-penetrating element in accordance with the present invention.

      Figure 7m is a longitudinal sectional view of a distal portion of the thirteenth embodiment of a tissue-

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penetrating element in accordance with the present invention.

Figure 8a is a longitudinal sectional view of a first embodiment of an apparatus for modifying an  
5 interstitial passageway formed in accordance with the present invention.

Figure 8b is a longitudinal sectional view of a second embodiment of an apparatus for modifying an  
10 interstitial passageway formed in accordance with the present invention.

Figure 8c is a longitudinal sectional view of a third embodiment of an apparatus for modifying an  
interstitial passageway formed in accordance with the present invention.

Figure 8d is a longitudinal sectional view of a fourth embodiment of an apparatus for modifying an  
15 interstitial passageway formed in accordance with the present invention.

Figure 8e is a longitudinal sectional view of a fifth embodiment of an apparatus for modifying an  
20 interstitial passageway formed in accordance with the present invention.

Figure 8f is a longitudinal sectional view of a sixth embodiment of an apparatus for modifying an  
25 interstitial passageway formed in accordance with the present invention.

Figure 8g is a longitudinal sectional view of a seventh embodiment of an apparatus for modifying an  
30 interstitial passageway formed in accordance with the present invention.

Figure 8h is a longitudinal sectional view of a eighth embodiment of an apparatus for modifying an  
interstitial passageway formed in accordance with the present invention.

Figure 8h' is an elevational view of the device of  
35 Figure 8h being used to modify and arteriovenous blood

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flow passageway formed in accordance with the present invention.

Figure 8i is a longitudinal sectional view of a ninth embodiment of an apparatus for modifying an interstitial passageway formed in accordance with the present invention.

Figure 8j is a longitudinal sectional view of a tenth embodiment of an apparatus for modifying an interstitial passageway formed in accordance with the present invention.

Figure 9a is an elevational view of a first embodiment of a device usable to longitudinally compress an arteriovenous passageway formed in accordance with the present invention.

Figure 9a' is an exploded perspective view of the device shown in Figure 9a.

Figure 9b is an elevational view of a second embodiment of a device usable to longitudinally compress an arteriovenous blood flow passageway in accordance with the present invention.

Figure 9b' is a partial longitudinal sectional view of the device of Figure 9b mounted within a delivery catheter.

Figure 9b'' is a perspective view of the device of Figure 9b partially ejected from its delivery catheter.

Figure 9b''' is a perspective view of the device of Figure 9b fully ejected from its delivery catheter.

Figure 9c is an elevational view of a third embodiment of a device usable to longitudinally compress an arteriovenous blood flow passageway in accordance with the present invention.

Figure 9d is an elevational view of a fourth embodiment of a device usable to longitudinally compress an arteriovenous blood flow passageway in accordance with the present invention.

Figure 9e is an elevational view of a fifth embodiment of a device usable to longitudinally compress

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an arteriovenous blood flow passageway in accordance with the present invention.

Figure 9f is an elevational view of a sixth embodiment of a device usable to longitudinally compress an arteriovenous blood flow passageway in accordance with the present invention.

Figure 9f' is a partial longitudinal sectional view of the device of Figure 9f mounted within a delivery catheter.

Figure 9f'' is a perspective view of the device of Figure 9f as it is mounted within its delivery catheter.

Figure 9f''' is a longitudinal sectional view of the device of Figure 9f partially deployed out of its delivery catheter.

Figure 9f'''' is a cross sectional view of the device of Figure 9f fully deployed out of its delivery catheter.

Figure 10a is a perspective view of a first embodiment of a transvascular tissue-penetrating catheter device of the present invention.

Figure 10b is a longitudinal sectional view through line 10b-10b of Figure 10.

Figure 10c is a longitudinal sectional view through line 10c of Figure 10a.

Figure 10d is a cross sectional view through line 10d-10d of Figure 10a.

Figure 10c' is a schematic view of an optional guide wire/sheath urging apparatus which may be incorporated into any embodiment of the transvascular tissue-penetrating catheter of the present invention.

Figure 10c'' is a schematic showing of the apparatus of Figure 10c' as the tissue-penetrating element of the catheter device is penetrating through tissue.

Figure 10c''' is a schematic showing of the device of Figure 10c after the tissue-penetrating element has penetrated through tissue and into a vascular lumen or open cavity.

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Figure 11a is a longitudinal section view through the handpiece component of a second embodiment of a transvascular tissue-penetrating catheter device of the present invention.

5        Figure 11b is a partial longitudinal sectional view through a distal portion of the second embodiment of the transvascular tissue-penetrating catheter device of the present invention.

10       Figure 11c is a longitudinal section showing of the device of Figure 11b during a first stage of a tissue-penetrating procedure.

Figure 11c is a longitudinal section showing of the device of Figure 11b during a second stage of a tissue-penetrating procedure.

15       Figure 11d is an enlarged longitudinal sectional view of segment 11d of Figure 11c.

#### **Detailed Description of the Preferred Embodiments**

The following detailed description and the drawings to which it refers are provided for the purpose of describing certain presently preferred embodiments of the present invention only, and are not intended to limit the scope of the invention in any way. Indeed, it is to be appreciated that the detailed descriptions and examples set forth herebelow are provided as mere examples or illustrations of certain ways in which the invention may be utilized or practiced. These examples and illustrations are not intended to provide an exhaustive description of all possible embodiments and examples of the invention but, rather, are illustrative of some but not all applications to which the invention may be applied.

#### **A. The Methods of the Present Invention**

##### **i. Revascularization Methods**

35       Broadly stated, the revascularization method of the present invention provides a method for establishing one or more passageway(s) 10 through which blood may flow from or into at least one blood vessel. In most cases,

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the blood which flows through the passageway will preferably have a  $pO_2$  in excess of about 50.

In some instances the extravascular passageway(s) 10 will be used for bypassing an obstructed, injured or disease-affected segment of an artery. In some embodiments of the invention, only a primary blood flow passageway (e.g., a passageway from the artery upstream of the obstruction) will be formed between an obstructed injured or disease-affected artery (or another unimpaired artery or a blood-filled anatomical structure such as a chamber of the heart), and a vein thereby permitting arterial blood will then be permitted to flow in the retrograde direction through the vein, so as to retroperfuse tissues through the venous vasculature. In other embodiments of the invention, one or more secondary blood flow passageways will also be formed between the obstructed artery and the vein, downstream of the obstruction, such that arterial blood which has entered the lumen of the vein through the primary blood flow passageway(s) may subsequently enter or re-enter the lumen of the artery, downstream of the obstruction, thereby perfusing tissues through the remaining (e.g., unobstructed) portion of the obstructed artery.

Although the anatomical showings provided in Figures 1a and 1b are specific to the coronary vasculature, it is to be appreciated that the methods of the present invention may be applied to blood vessels throughout the body and are not necessarily limited the treatment of obstructed coronary arteries (e.g., the femoral-popliteal region, aorta-iliac region, etc.).

With reference to the drawings, Figures 1a and 1b provide detailed showings of the normal vascular anatomy of a human heart wherein coronary arteries are substantially parallel and adjacent to coronary veins. The specific anatomical structures shown in Figures 1a, 1b and 1c are labeled in accordance with the following legend:

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	A . . . . .	Aorta
	AIV . . . . .	Anterior Interventricular Vein
	CA . . . . .	Coronary Artery
	CV . . . . .	Coronary Vein
5	CS . . . . .	Coronary Sinus
	CIR . . . . .	Circumflex Artery
	IVC . . . . .	Inferior Vena Cava
	LAD . . . . .	Left Anterior Descending Artery
	SVC . . . . .	Superior Vena Cava
10	PA . . . . .	Pulmonary Artery
	PV . . . . .	Pulmonary Vein
	TA . . . . .	Tunica Adventitia
	TM . . . . .	Tunica Media
	TI . . . . .	Tunica Intima
15	GCV . . . . .	Great Cardiac Vein

Figures 1c-1d illustrate a specific application of the present invention, wherein an obstruction OB is located within a coronary artery located on the left anterior aspect of the heart. As shown, the obstructed coronary artery CA is located adjacent, and generally parallel to, a coronary vein CV. A first blood flow passageway 10a is formed between the coronary artery CA and the adjacent coronary vein CV, at a location upstream of the arterial obstruction OB. Also, in the showing of Figure 1c, an optional second blood flow passageway 10b has been formed between the lumen of the coronary vein CV and the lumen of the coronary artery CA, at a location downstream of the obstruction OB. Also, in these figures, optional embolization members 12a, 12b are shown to have been placed within the lumen of the coronary vein CV at sites proximal of the first blood flow passageway 10a, and distal of the optional second blood flow passageway 10b. These optional embolization member serve to guide the flow of arterial blood which enters the coronary artery CA through the first blood flow passageway 10a, through a segment of the adjacent coronary vein CV, and through the second blood flow

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passageway 10b such that the arterial blood reenters the lumen of the coronary artery CA, downstream of the obstruction OB. Optional embolization members 12a, 12b may be any one or combination of devices sufficient to  
5 block or impede flow such as coils; hemostatic materials such as collagen, Gelfoam™ or fibrin, covered stents or frames, detachable balloons, valve structures clips, fasteners or plugs, etc. Further, the function served by these members may also be accomplished utilizing various  
10 methods including ligation, welding, coagulation, or other surgical methods.

As illustrated in the cross sectional showing of Figure 1d, each blood flow passageway 10 of the present invention is essentially an interstitial tunnel which  
15 extends through the wall of an artery (such as a coronary artery CA) through the wall of an adjacent vein (such as a coronary vein CV) and through any connective or membranous tissue which may be located between the coronary artery CA and coronary vein CV. In this manner,  
20 each blood flow passageway 10 acts as a flow conduit between the lumens of the coronary artery CA and coronary vein CV.

Figure 1e is a diagram of a portion of the coronary vasculature known as the Triangle of Brouck-Moscheau.  
25 The Triangle of Brouck-Moscheau is defined by the left anterior descending coronary artery LAD, the circumflex coronary artery CIR, the anterior interventricular vein AIV and the great cardiac vein, GCV, as shown. Obstructions resulting from the build-up of  
30 atherosclerotic plaque are often found in the proximal portions of the left anterior descending artery LAD and/or the circumflex artery CIR. The revascularization methods of the present invention may be utilized to treat such obstructions of the left anterior descending artery  
35 LAD and/or circumflex artery CIR by forming appropriate blood flow passageways 10 between the arteries and veins surrounding the Triangle of Bouck-Moscheau. For example,

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if an obstruction is present in the proximal portion of the left anterior descending artery LAD, a first blood flow passageway 10a may be formed between the great cardiac vein GCV and the circumflex artery CIR and a second blood flow passageway 10b may be formed between the left anterior descending artery LAD and the anterior intraventricular artery AIV, at a location downstream of the obstruction. A lumen blocking member 12 may be placed within the great cardiac vein GCV, proximal to the first blood flow passageway 10a and/or within the anterior interventricular vein AIV distal to the second blood flow passageway 10b such that arterial blood from the circumflex artery CIR will flow through the first blood flow passageway 10a, through the great cardiac vein GCV, through the anterior interventricular vein AIV and into the left anterior descending artery LAD, downstream of the obstruction. Alternatively, in cases where the obstruction is present in the circumflex artery CIR, the first blood flow passageway 10a and second blood flow passageway 10b may be inverted, such that blood flowing through the left anterior descending artery LAD will flow through the anterior interventricular vein AIV, through the great cardiac vein GCV and into the circumflex artery CIR, downstream of the obstruction. In accordance with these examples, it will be appreciated that the revascularization method of the present invention may be utilized in a manner which obtains arterial blood from an artery or from any other source (e.g., left ventricle), and passes such arterial blood into another artery. Moreover, in accordance with the revascularization methods of the present invention, it will be appreciated that the second blood flow passageway 10b may, in at least some cases, be eliminated and arterial blood may be provided to the blood-deprived regions of the myocardium by retroprofusion through the anterior interventricular vein AIV or great cardiac vein GCV.

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It will be appreciated that in some applications of the revascularization method of the present invention, the extravascular passageway 10 may comprise an interstitial tunnel which extends from a first location to a second location, on the same blood vessel. As shown in Figure 1f, a blood vessel BV having an obstruction OB formed therein may be bypassed by utilizing a passageway-forming catheter 100 of the present invention whereby a tissue-penetrating element 102 is passed through the wall of the blood vessel upstream of the obstruction, through the adjacent tissue, and subsequently through the wall of the blood vessel downstream of the obstruction. In this manner, an interstitial passageway 10, shown in Figure 1f', forms a bypass conduit around the obstruction OB in the blood vessel BV.

ii. Methods for Performing Surgical or Interventional Procedures at Extravascular Locations

In addition to the above-described revascularization methods, the present invention also includes methods for performing various surgical or interventional procedures at extravascular locations within the body. These methods of the present invention are accomplished by forming one or more extravascular passageways from a blood vessel to an extravascular location (e.g., organ, tissue, body cavity, etc.) and subsequently passing one or more procedure-performing apparatus through the extravascular passageway to accomplish the desired surgical or interventional procedure at the extravascular location. The types of surgical or interventional procedures which may be performed in accordance with this method of the present invention include:

DELIVERY OF THERAPEUTIC MATTER

- Delivery of flowable drug substance;
- Implantation of an implantable drug delivery apparatus (e.g., microspheres, etc.);
- Delivery of medical treatment fluids;

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- Implantation of access catheter for ongoing drug dosing;
- Implantation of genetic material, cells, microbial or viral vectors, etc.

5     **TEMPORARY OR PERMANENT DEPLOYMENT OF DEVICE(S)**

- Implantation of stimulator (electrical or physical);
- Implantation of sensor;
- Implantation of electrode;
- 10    • Implantation of transmitter, receiver or transponder;
- Implantation of support member (e.g., stent);
- Implantation of marker (e.g., radiographically visible markers, or solutions.

15    **TISSUE RESECTION, EXCISION OR ABLATION**

- Tissue ablation or destruction;
- Cutting or transection of tissue (e.g., nerve, fibers);
- Resection and removal of neoplasms, diseased
- 20    tissue, etc.;
- Dilation, stretching or other modification of endogenous tissue to restore patency, flow, configuration, or function.

**SAMPLING APPLICATIONS**

- 25    • Sampling of tissue (e.g., biopsy);
- Sampling of solid matter (e.g., calculus, tophi, etc.);

**MONITORING APPLICATIONS**

- 30    • Determining pressure, pH, temperature, oxygen saturation, partial pressure of dissolved gas, ECG, EEG, evoked potentials, or other variables which are measurable at the target area.

      Figures 2-2f are provided for the purpose of further describing and illustrating some of the specific

35    interventional and/or surgical procedures which may be performed in accordance with this embodiment of the present invention.     Figure 2 shows a schematic

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illustration of the human body wherein a passageway-forming catheter apparatus 100 of the present invention has been percutaneously inserted into a blood vessel (e.g., femoral vein) and has been advanced through the vena cava, internal jugular vein and great cerebral vein, to a desired location adjacent the extravascular target area (e.g., ventricle of the brain). Thereafter, a tissue-penetrating element 102 is passed from the catheter 100 through the wall of cerebral blood vessel wherein the distal portion of the catheter 100 is located and the tissue penetrating element is advanced through the adjacent brain tissue to an extravascular target location T within the brain. In this manner, an extravascular passageway 10 has been formed from the cerebral blood vessel to the extravascular target location T. As necessary, the passageway 10 which is initially formed by the tissue-penetrating element 102 may be debulked, enlarged or modified in accordance with the apparatus and methods for passageway modification shown in Figures 8a-8h and described in detail herebelow.

Figure 2a is an enlarged view of the target area T and the adjacent blood vessel BV into which the passageway-forming catheter device 100 has been advanced. Initially, the tissue-penetrating element 102 of the passageway-forming catheter device 100 is advanced out of the catheter 100, through the wall of the blood vessel BV, and through tissue which is located between the blood vessel BV and the target area T. The tissue-penetrating element 102 utilized in this application preferably incorporates a lumen 114 through which a secondary guide wire  $GW_2$  may be advanced into the target area T. Thereafter, the tissue-penetrating element 102 may be retracted and removed along with the passageway-forming catheter 100, leaving the secondary guide wire  $GW_2$  in place.

As shown in Figure 2a, an access canula 103 may then be advanced over the pre-positioned secondary guide wire

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GW<sub>2</sub> such that the cannula 103 extends through the vasculature, through the extravascular passageway 10 formed by the tissue-penetrating element 102 and into the target area T. This access cannula may then be utilized  
5 as a conduit for introduction of drugs, implantation of devices, sampling, monitoring, deployment of surgical apparatus or other applications in accordance with the methods for performing surgical or interventional procedures at extravascular locations, described  
10 hereabove.

Figures 2b-2f illustrate specific examples of the types of extravascular surgical or interventional procedures which may be performed in accordance with this aspect of the invention.

15 With reference to Figure 2b, a subcutaneous port apparatus 105 may be mounted on the proximal end of the access cannula 103, and may be utilized for the injection or withdrawal of flowable substances (e.g., drugs, medical treatment fluids, radiographic contrast  
20 solutions, cells, genetic material, microbial or viral vectors, etc.) through the access cannula 103, and into the target area T. Also, the port apparatus 105 and cannula 103 may be utilized to accomplish periodic monitoring of pressure or other conditions at the target  
25 area T (e.g., by filling the cannula 103 with fluid and inserting a needle connected to a pressure transducer into the port apparatus 105, a reading of pressure at the target area T may be obtained). Thus, Figure 2b illustrates the manner in which an indwelling access  
30 cannula 103 having a subcutaneously positioned injection port 105 may be utilized for continuing infusion or withdrawal of flowable matter into/from the target area T. Specific examples of the types of conditions which may be treated by repeated infusions of drugs to a  
35 specific target area T within the body include Parkinsons disease, epilepsy, hypertension, tumors, depression, Alzheimer's disease, sleep disorders, behavior disorders,

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motor dysfunctions, etc. Additionally, the access cannula 103 and injection port 105 may be used as a means for periodically infusing replacement fluids or solutions, to effect various types of replacement therapies. These applications may also be performed with the device shown in Figure 2c.

Figure 2c shows an alternative arrangement wherein the access cannula 103 is exteriorized and is utilized as a conduit for the passage of a temporary device 106 into the target area T. The device 106 may be connected to an extracorporeal apparatus 107 which will deliver some form of energy to the device 106, or will receive information from the device 106. Examples of the types of extracorporeal apparatus 107 which may be utilized include, but are not necessarily limited to, electrical signal generators, electrocautery apparatus, radio frequency signal generators, cryogenic apparatus, ultrasound generators, form of oscilloscopes, monitors, chart recorders, galvanometers, laser, scopes, other instrumentation, etc. Specific examples of the types of treatments which may be delivered to the target area T by way of a temporarily positioned device 106 include radio frequency ablation of tissue (e.g., nerve tracts or arrhythmogenic tracts within the heart) cryogenic tissue destruction (e.g., of a tumor), electrocautery (e.g., to stop a hemorrhage or ablate tissue), etc. Examples of the types of monitoring or information retrieval operations which may be utilized in connection with a temporarily-positioned device 106 include localized EEG measurements, localized ECG measurements. Recordation of galvanometric responses, oxygen saturation measurements, partial pressure measurements of gasses dissolved in fluids, pH measurements, electrode determinations of the concentrations of specific electrolytes or other chemical substances, etc.

Figure 2d shows an application of the present invention wherein the access cannula 103 is utilized to

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continually drain fluid from the target area T. In this manner, the proximal portion of the access cannula 103 is provided with a plurality of outlet apertures 109 such that excess fluid which collects within the target area T will drain proximally through the lumen of the access cannula 103 and out of outlet apertures 109. The proximal portion of the access cannula 103 having the outlet apertures 109 formed therein may be exteriorized such that excess fluid is drained into an extracorporeally located container or vessel, or alternatively be implanted at another location within the body (e.g., the peritoneal cavity) such that excess fluid will pass into such other area of the body where it can be assimilated by natural physiologic functions without causing damage or harm to the body. One example of such application is the use of the cannula 103 as an indwelling shunt or draining excess cerebrospinal fluid from a ventricle of the brain to a secondary location (e.g., peritoneum) within the body. Because the cannula 103 has been implanted through the vasculature and through the extravascular passageway 10 created in accordance with the invention, the technique used for implantation of the cannula 103 may be performed percutaneously without requiring large surgical incisions as may be typical of other methods utilized to implant fluid-drainage shunt devices used for the treatment of hydrocephalus and other disorders.

Figure 2e shows another specific application of the present invention, wherein the access cannula 103 extends from the blood vessel BV, through the extravascular passageway 10 of the present invention and into the lumen 111 of a secondary tubular anatomical passageway or duct which is the target T in this application. The types of tubular passageways or ducts which may form the target T in this application of the invention include blood vessels, geneto-urinary ducts, exocrine ducts, endocrine ducts and lymph ducts. After the access cannula 103 has

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been positioned within the lumen 111 of the target duct or passageway T, any of the above-listed applications for this methodology may be utilized including withdrawal of samples of infusion of drugs, deployment of devices, etc.

5        Figure 2f illustrates yet another specific example of an application of the invention wherein the access cannula 103 extends through the vasculature, through an extravascular passageway 10 of the present invention, and into a target area T such that one or more surgical  
10        instruments 113 may be passed into the target area T for the purpose of performing a surgical (e.g., micro-surgical) procedure within the target area T. In this manner, an exteriorized control system 115 may be connected to the surgical instrument(s) 113 and may be  
15        utilized to effect the desired operation and manipulation of the surgical instrument 113 within the target area T.

**iii. Types of Passageways**

      Figures 3a-3f, and the detailed description set forth herebelow, describe certain types of extravascular  
20        passageways 10 which may be formed in accordance with the present invention. The showings of Figures 3a-3f and the following detailed description are presented as mere examples of types of passageways which may be formed, and are not intended to exhaustively describe all possible  
25        types of passageways 10 which may be utilized in accordance with the present invention. Furthermore, it is to be noted that although the showings of Figures 3a-3f are directed to passageways 10 formed between a vein and artery, the various passageway modifications  
30        illustrated in Figures 3a-3f are broadly applicable to any or all types of extravascular passageways 10 formed in accordance with the present invention, for which such modifications may be suitable. Indeed, the passageways 10 shown in Figures 3a-3f and described herebelow are not  
35        limited to passageways formed between arteries and veins, but may be broadly applicable to all passageways 10 of the present invention.

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As shown in Figures 3a, the passageways 10 of the present invention may comprise unstented, unlined, interstitial tunnels (Fig. 3a). Alternatively, as shown in Figures 3b-3f, such passageways 10 may be provided with various types of surface modifications or ancillary apparatus, such as tubular linings (Fig. 3b), longitudinal constraining clips (Fig. 3c), stents or stented grafts which are confined to the interior of the passageway 10 (Fig. 3d), or stents or stented grafts which protrude out of and beyond the passageway 10 (Figs. 3e-3f).

Referring specifically to Figure 3a, there is shown a passageway 10 which extends between two blood vessels and which is devoid of any stent, liner, tubing, coating, valve, surface modification, substance or apparatus disposed within the passageway 10. In this regard, this unstented, unlined, unmodified passageway 10 is simply an interstitial tunnel (e.g., a puncture tract or tunnel) which extends between two blood vessels such that blood may flow from the lumen of one blood vessel into the lumen of the other.

Figure 3b shows a passageway 10 formed between two blood vessels and having a tubular inner lining 20 disposed therewithin. Such inner lining 20 may comprise a segment of rigid or flexible plastic tubing, a layer of a biocompatible polymeric coating, a layer of cells of a type which differs from that of the surrounding tissue (e.g., endothelial layer biological tissue graft, etc.), a layer of tissue of modified density as may be formed by laser treatment, electrocautery, etc., or any other type of matter which differs from the inner surface of the unstented and unlined passageway 10 itself. Such lining 20 within the passageway 10 may serve to a) facilitate laminar and non-turbulent blood flow through the passageway 10 or b) prevent unwanted closure of the passageway due to natural contraction of surrounding muscle or tissue ingrowth into the passageway 10. In

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instances wherein the lining 20 is formed by application of a flowable material or energy (e.g., a chemical substance to produce a controlled chemical burn of the tissue or a biocompatible polymer coating, a suspension of endothelial cells, etc...) to the walls of the passageway 10, the application of such flowable material to the wall(s) of the passageway 10 may be accomplished through the use of a device such as that shown in Figures 8h-8h'' and discussed more fully herebelow, in reference to the devices of the present invention.

Figure 3c shows a passageway 10 wherein a longitudinal constraining apparatus 22 has been positioned so as to longitudinally compress the opposite ends of the passageway 10 toward one another, thereby compacting any tissue (e.g., loose connective tissue) which is located between the blood vessels. Such longitudinal constraining apparatus 22 may also be constructed to provide radial support for, and/or maintain patency of the passageway 10. The application of longitudinal compression to the passageway 10 by a constraining apparatus 22 may be particularly important in applications of the invention wherein the blood vessels which the passageway 10 connects are located on the surface of an organ (e.g., epicardially located coronary artery and vein), or are otherwise located such that cavernous or loose tissue (e.g., loose connective tissue) or open space exists between the artery and vein. The presence of such cavernous or loose tissue may allow blood which flows through the passageway 10 to infiltrate into such tissue or space between the artery and vein, as may result in the formation of a hematoma. Examples of specific types of constraining apparatus 22 which may be utilized to longitudinally compress the blood flow passageway 10 as shown in Figure 2c, or to otherwise facilitate coupling of two blood vessels by side-to-side anastomosis, are shown in Figures 9a-9f, and are

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described more fully herebelow with reference to Figures 9a-9f.

Figure 3d shows a passageway 10 of the present invention having a non-protrusive stent or stented graft 24 positioned within the passageway 10. Such stent or stented graft 24 may comprise a pressure-expandable or self-expanding cylindrical stent or frame work, and may optionally be covered by a continuous tubular member such as a pliable segment of woven polyester or expanded polytetrafluoroethylene (ePTFE) the disposition of such stent or stented graft 24 within the passageway 10 may serve to hold the passageway 10 in a substantially open configuration to facilitate non-turbulent blood flow through the passageway 10. The stent or stented graft 24 may be formed of any suitable material including, but not necessarily limited to, various types of pressure expandable or self-expanding wire mesh or interwoven strands of polymeric material. In instances where a stented graft 24 is utilized, the tubular graft covering on the stented graft 24 may be continuous or may be partial, such that only a portion of the stent is covered.

It will be appreciated that when a protrusive stented graft (e.g., covered stent 26 or 28) is utilized, it may be unnecessary to additionally position the optional embolization members 12 within the lumen of the blood vessel into which the stented graft 26, 28 extend, as the tubular outer covering on the stented graft will serve to define a closed flow conduit through the lumen of that blood vessel and will substantially block the flow of endogenous blood through that portion of the blood vessel, thereby obviating any need for separate embolization members 12.

Figure 3d' shows modifications of the stent or stented graft 24a to include a flange 25 and/or perpendicular projections 27 extending from one or both end(s) of the stent or stented graft 24a to hold the

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stent or stented graft 24a in substantially fixed longitudinal position within the passageway 10.

Figure 3e shows a hemiprotrusive or protrusive stent or stented graft 26 which may be constructed in the same manner as the non-protrusive stent or stented graft 24 shown in Figure 3d, but which differs from that shown in Figure 3d in that it protrudes or extends beyond the ends of the passageway 10, into adjacent portions of the artery A and vein. When so deployed, this stent or stented graft 26 will generally assume an "S" configuration, as shown in Figure 3e, to facilitate laminar, non-turbulent flow of blood in the desired direction through the passageway 10. The dotted lines on Figure 3e illustrate a "hemiprotrusive" embodiment of the stent or stented graft 26 wherein one end thereof is flush with one end of the passageway 10, while the other end thereof extends into the anatomical structure (i.e., vein) adjacent that end of the passageway 10. Such "hemiprotrusive" embodiment of the stent or stented graft 26 may be employed so as not to obstruct any available blood flow through the artery A, and will be particularly applicable in patients in whom the obstruction OB is not complete, and in whom some arterial blood flow continues to pass through the artery A. In other patients wherein the obstruction OB is complete, it may be appropriate to use the full "protrusive" embodiment of the stent or stented graft 26 wherein such stent or stented graft 26 extends out of both ends of the passageway 10 into the adjacent anatomical structures (i.e., vein and artery), as indicated by the dotted lines on Figure 3e.

Figure 3f shows another protrusive stent or stented graft 28 which extends fully through a first blood flow passageway 10a and an optional second blood flow passageway 10b, and which additionally protrudes through adjacent portions of the artery A and vein V, thereby forming a continuous "U"-shaped conduit through which

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laminar, non-turbulent blood flow may pass through both passageways 10a, 10b.

It will be appreciated that one or more valves may also be formed within any embodiment of the stent or stented graft 24, 26, 28 or within a tubular lining 20, or within a longitudinal constraining apparatus 22, or otherwise within the passageway 10, to facilitate the flow of blood in a desired direction(s) through the passageway(s) 10 while deterring or preventing blood from backflowing through the passageway(s) 10 in direction(s) opposite the desired direction(s).

iv. Transvascular Approaches for Forming the Passageway(s) Between Two Blood Vessels

Figures 4a-4e and the following detailed description, are provided for the purpose of illustrating some approaches which may be utilized for forming extravascular passageways 10 between two blood vessels, to accomplish certain revascularization methods of the present invention. The showings of Figures 4a-4e and the following detailed description are not intended to exhaustively illustrate all possible approaches which may be utilized for forming such passageways 10, but rather are provided as mere examples of presently perceived approaches for such procedures. Furthermore, although the showings of Figures 4a-4e illustrate applications wherein an obstruction OB is present within one of the blood vessels, the general approach is illustrated in these figures may be applicable to various revascularization methods wherein the passageways 10 are formed for purposes other than bypassing obstructions, or wherein the obstructions OB are located remotely from the locations at which the passageway(s) 10 are formed. Furthermore, it is to be appreciated that the approach is illustrated in Figures 4a-4c need not necessarily be performed between two blood vessels or between an artery and vein. Indeed, these approaches may be applicable between any blood vessel and any other hollow anatomical

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structure, and may be useable for vein to vein, artery to artery or vein to artery passageway(s) 10.

Figure 4a shows one type of approach wherein a catheter 100 is advanced transluminally into an artery A and a tissue-penetrating element 102 is passed from the catheter 100 to form a first passageway 10a through the wall of the artery A, through a tissue located between the artery A and vein V, and through the wall of the vein. After the first blood flow passageway 10a has been created in this manner, a guide wire may be passed through the tissue-penetrating element 102 or through the catheter 100, and through the newly-created first passageway 10a. Thereafter, the tissue penetrating element is deactivated (e.g., retracted into the catheter 100), and the catheter is advanced over the guide wire, through the first passageway 10a, and into the lumen of the vein, past the site of the obstruction OB in the adjacent artery A. Thereafter, with the distal portion of the catheter positioned within the lumen of the vein, the tissue penetrating element 102 is once again advanced out of the catheter 100 to form a second blood flow passageway 102 which extends through the wall of the vein, any tissue located between the vein and artery A, and through the wall of the artery A. Thereafter, the tissue penetrating element 102 may be once again retracted into the catheter 100 and the catheter may be retracted from the vasculature and out of the body. In this manner, the approach shown in Figure 4a, accomplishes formation of a first blood flow passageway 10a upstream of the arterial obstruction OB and a second blood flow passageway 10b downstream of the arterial obstruction.

Figure 4b shows an alternative approach wherein a catheter 100 is transluminally advanced into the lumen of a vein, and the distal end of the catheter is positioned adjacent the location at which the first blood flow passageway 10a is to be created. Thereafter, the tissue

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penetrating element 102 is passed out of the catheter 100 to form the first blood flow passageway 10a through the wall of vein V, any tissue between the vein V and artery A, and through the wall of the artery A. Thereafter, the tissue penetrating element 102 is deactivated (e.g., retracted into the catheter 100), and the catheter is advanced further through the vein V until the distal end of the catheter is located adjacent the location at which the second blood flow passageway 10b is to be created. Thereafter the tissue penetrating element 102 is once again passed out of the catheter 100, to form the desired second passageway 10b through the wall of the vein V, and tissue between the vein V and artery A, and through the wall of the artery A. Thereafter, the tissue penetrating element 102 is once again deactivated (e.g., retracted into the catheter 100) and the catheter 100 may be extracted from the venous vasculature and removed. In this manner, the approach depicted in Figure 4b accomplishes the formation of a first blood flow passageway 10a downstream of the arterial obstruction OB and a second blood flow passageway 10b upstream of the arterial obstruction OB, by cannulation and transluminal catheterization of the vein V only.

Figure 4c shows another alternative approach wherein a catheter 100 is transluminally advanced into an artery A, and the distal end of the catheter 100 is positioned adjacent the site at which the first blood flow passageway 10a is to be formed. Thereafter, the tissue-penetrating element 102 is passed out of the catheter 100 to form the first blood flow passageway 10a through the wall of the artery, any tissue between the artery A and vein V, and through the wall of the vein V. Thereafter, the tissue penetrating element 102 is deactivated (e.g., retracted into the catheter 100) and the catheter is further advanced through the lumen of the artery A and is passed through the obstruction OB until the distal end of the catheter 100 is located adjacent the site at which

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the second blood flow passageway 10b is to be formed. Such advancement of the catheter 100 through the obstruction OB will typically require that a guide wire be initially advanced through the obstruction OB to facilitate subsequent advancement of the catheter 100 through the obstruction OB. Such initial passage of a guide wire through the obstruction OB may be accomplished in cases where the obstruction OB is partial, or where the obstructive material is soft enough to permit a guide wire to penetrate therethrough. However, in cases where the obstruction OB is complete or formed of calcified plaque or other hard matter, the approach shown in Figure 4c may be less than viable and the operator will typically opt for one of the approaches shown in Figures 4a or 4b in such cases. However, in cases where the catheter 100 has been successfully advanced through the obstruction OB as shown in Figure 4c, the tissue penetrating element 102 will then be once again advanced out of the catheter 100 to create the second blood flow passageway 10b through the wall of the artery 10a, any tissue between the artery A and vein V, and through the wall of the vein V. Thereafter, the tissue-penetrating element 102 will be deactivated (e.g., retracted into the catheter 100) and the catheter will be extracted from the arterial vasculature and removed from the body. In this manner, the approach shown in Figure 4c accomplishes formation of a first blood flow passageway 10a and second blood flow passageway 10b in accordance with the present invention.

Figure 4d shows another alternative approach wherein a catheter 100 is provided with a positive pressure pumping 104 for pumping positive pressure fluid (e.g., saline solution) through the catheter and out of a plurality of positive pressure outlet apertures 106 formed in the body of the catheter 100 near the distal end thereof. A proximal sealing member 108 (e.g., a balloon which completely blocks the blood vessel lumen)

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is formed on the catheter, proximal to the positive pressure outlet apertures 106. A separate distal sealing (e.g., a balloon) 110 is placed within the lumen of the vein V, slightly upstream of the site where the second blood flow passageway 10b is to be created. The catheter 100 is advanced through the lumen of the vein V until the distal end of the catheter is positioned adjacent the site of at which the second blood flow passageway 10b is to be created. Thereafter, the proximal sealing member 108 is deployed (e.g., inflated) so as to completely seal the vein V proximal to the positive pressure outlet apertures 106 of the catheter 100. Thereafter, positive pressure fluid (e.g., saline solution) is passed through a lumen of the catheter and out of the positive pressure outlet apertures 106, to cause the pressure  $P_1$  within the vein V to become elevated and, preferably, substantially equal to the mean pressure  $P_2$  within the artery A. Such pressurization of the lumen of the vein V provides a viable method of identifying the presence of any venous side branches SB which may require ligation, closure or embolization so as to prevent any significant steal of blood from the newly-created venous bypass conduit. Additionally, such pressurization of a lumen of the vein V may be maintained while the tissue-penetrating element 102 is advanced out of the catheter 100, through the wall of the vein V and through the wall of the artery A to form the passageway 10 of the present invention. Such equalization of the pressure  $P_1$  within the vein V to the pressure  $P_2$  within the artery also serves to prevent any rapid gush or flow of blood from the lumen of the artery A into the lumen of the vein V when the passageway 10 is created.

Figure 4e shows another alternative approach wherein a first catheter 100 is advanced into the artery A, and a second catheter 100 is advanced into the vein V. In some instances, the first and second catheters 100 will be advanced in generally opposite directions, as shown in

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Figure 4e. Thereafter, the tissue-penetrating elements 102 of the respective catheters 100 are utilized to form first and second blood flow passageways 10a, 10b between the artery A and vein V, as shown. Thereafter, the tissue-penetrating elements 102 will be deactivated (e.g., retracted into the catheters 100) and the catheters 100 will be extracted from the vasculature and removed from the body. In this manner, the approach shown in Figure 4e accomplishes the formation of first and second blood flow passageways 10a and 10b between the desired blood vessels, in accordance with the present invention.

v. Methods and Apparatus for Controlling, Aiming and Guiding a Tissue-Penetrating Element and/or Ancillary Devices Used to Form the Extravascular Passageway(s)

Figures 5a-5l show examples of apparatus which may be utilized for orienting, aiming, controlling and/or guiding the tissue-penetrating element 102 as it is advanced from the catheter 100 of the present invention, to create desired extravascular passageway 10. In general, these orienting, aiming, controlling and guiding apparatus are intended to position the catheter 100 such that, when the tissue-penetrating element 102 is passed out of the catheter 100 it will come into contact with and penetrate the wall of the blood vessel within which the catheter 100 is positioned. It is to be appreciated that the drawings set forth in Figures 5a-5l and the following detailed description are provided as mere examples of the types of orienting, aiming, controlling and/or guiding apparatus which may be utilized in the present invention, and are not intended to exhaustively show or describe all possible apparatus which may be used for these purposes. Furthermore, it is to be understood that any or all of the apparatus shown in Figures 5a-5l and described herebelow may be combined with any other element of the invention described herein to form a "system" whereby the passageway-forming catheters 100 of

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the present invention may be oriented, aimed, controlled or guided.

Figure 5a shows one approach wherein an active imaging device 50 is positioned within the same blood vessel as the catheter 100 of the present invention. This active imaging device 50 may comprise any suitable type of catheter borne imaging device, including, but not limited, to an intravascular ultrasound apparatus (IVUS catheter), a Doppler apparatus, an angioscope, etc. In many instances, the active imaging device 50 will have a sensor (e.g., ultrasound transducer, sonic transducer, form image-receiving lens, etc.) formed at a specific location thereon. It will typically be desirable for such sensor 52 to be located immediately adjacent the location at which the tissue-penetrating element 102 is to enter the blood vessel wall in order to provide the desired observation, aiming and guidance of the tissue-penetrating element 102. It will be appreciated, that the active imaging device 50 may be mounted upon or formed internally of the passageway-forming catheter 100, may be carried within a monorail or sidecar formed on the catheter 100 (see Figs. 9-10), or may be located within a wholly separate and discreet catheter body, as is shown in Figure 5a. Embodiments of the a passageway-forming catheter device 100 which incorporate means for mounting of at least a distal portion of the active imaging device 50 within the passageway-creating catheter 100 are specifically shown in Figures 9-10, and are fully described herebelow with reference to such figures.

One alternative approach for observing, aiming and guiding the tissue-penetrating element 102 is shown in Figure 5b, wherein the active imaging device 50 is positioned within the blood vessel into which the tissue-penetrating element 102 of the, passageway-creating catheter 100 will pass. As shown in Figure 5b, the sensor 52 of the imaging device 50 may be located immediately adjacent the site at which the passageway 10

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is to be formed, such that the sensor 52 may aim and guide the tissue-penetrating element 102 as it extends from catheter 100, toward the sensor 52 of the active imaging device 50.

5        Figure 5c shows another alternative approach which incorporates the use of a secondary imaging apparatus 54 (e.g., a passive or co-active apparatus) in addition to the primary active imaging device 50. This secondary imaging apparatus may be formed on the passageway-creating catheter 100, or on the tissue-penetrating  
10        element 102 itself, and is capable of communicating with or being sensed by the preliminary imaging apparatus 50. The primary imaging device 50, having a sensor 52 located thereon is positioned in the blood vessel adjacent that  
15        in which the passageway-creating catheter 100 is located. The active imaging device 50 will sense or communicate with the secondary imaging apparatus 54 so as to provide direct means for observing, aiming and guiding the  
20        tissue-penetrating element 102. In this embodiment, the secondary imaging apparatus 54 may comprise any suitable type of substance or apparatus which is interrogable, imageable, or otherwise discernable by the active imaging  
25        device 50. For example, the sensor 52 of the active imaging device 50 may comprise a radio frequency transmitter and the secondary imaging apparatus 54 on the  
30        passageway-creating catheter 100 may comprise a radio frequency transponder which may be interrogated by, and will emit a responsive signal to, a radio signal emitted by the radio frequency transmitter of the active imaging  
35        device 50. Alternatively, in embodiments where the active imaging device 50 is a fluoroscope, intravascular ultrasound (IVUS) device or Doppler, the secondary imaging apparatus 54 on the passageway-forming catheter 100 may comprise a radio opaque marker, reflective surface or sounding aperture from which radiation, sonic or ultrasonic energy may be reflected back to the active imaging device 50. Examples of the types of sounding

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apertures or surfaces which may be formed on the body of the catheter 100 or tissue-penetrating element 102 to enhance visualization thereof by an active imaging device 50 are described in United States Patent No. 4,977,897 (Hurwitz).

Figure 5d shows a system wherein magnets 57a, 57b are mounted within modified passageway-forming catheters 101a, and are used in conjunction with a tissue-penetrating guide wire 103 having a sharpened distal tip 107, to form a passageway 10 between two blood vessels BV<sub>1</sub>, BV<sub>2</sub> as shown, each of the catheters 101a, 101b has a magnet 57a, 57b mounted in one side thereof. Each magnet, and adjacent inserts formed within the catheter body has a hollow lumen 109 extending therethrough. In this manner, the luminal openings in the magnets 57a, 57b may be positioned in direct alignment with one another, utilizing the attractive force of the magnets 57a, 57b to accomplish such aligned positioning. Thereafter, the tissue-penetrating guide wire 103 having the sharpened distal tip 107 may be advanced through the guide wire lumen 109a of the first catheter 101a and out of the luminal opening in the magnet 57a of that catheter 101a, through the wall of the first blood vessel BV<sub>1</sub>, through any tissue located between the first blood vessel BV<sub>1</sub>, and the second blood vessel BV<sub>2</sub>, through the wall of the second blood vessel BV<sub>2</sub> and into the luminal opening of the magnet 57b of the other passageway-forming catheter 101b. In this manner, the tissue-penetrating guide wire 103 will have formed a passageway 10 between the first blood vessel BV<sub>1</sub> and a second blood vessel BV<sub>2</sub>. It will be appreciated that the distal tip 107 of the tissue-penetrating guide wire 103 may comprise a sharp distal tip which is retractable into the guide wire such that the guide wire GW may remain within the blood vessels after the catheters 101a, 101b have been removed. Alternatively, the tissue-penetrating guide wire 103 may be a laser wire, hot wire or any other type of tissue-

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penetrating member suitable to form the desired passageway 10.

Figure 5e-5e''' show methods and apparatus whereby passive radiographically visible markers formed upon a passageway-forming catheter 100 of the present invention, may be utilized to effect precise rotational positioning of the catheter 100 prior to formation of each extravascular passageway 10. Figure 5e shows, in schematic fashion, a passageway-creating catheter 100 positioned within a first blood vessel  $BV_1$  with the intention of forming a passageway 10 in accordance with the present invention from the first blood vessel  $BV_1$  into an adjacent target T (e.g., a body cavity, mass of tissue or another blood vessel). A radiographic imaging apparatus 118 such as a fluoroscope or x-ray device is utilized to provide a radiographic image of the first blood vessel  $BV_1$  and second blood vessel  $BV_2$  on a screen 120 (e.g., an x-ray cassette or fluoroscopy screen).

Figure 5e' shows a catheter 100 having radiographically visible (e.g., radio-opaque or radio-lucent) markers 122a, 122b formed at longitudinally spaced apart locations on opposite sides of the catheter 100. These radiographically visible markers 122a and 122b are preferably at equivalent elevational positions relative to the height H of the catheter 100, but are spaced apart longitudinally, as shown. Thus, precise rotational positioning of the catheter 100 may be achieved by causing these radiographically visible markers 122a, 122b to become directly aligned on the screen 120 at equivalent elevational positions, as shown in the lower side box of Figure 5e'.

Figure 5e'' shows another type of passive marking system which may be utilized to achieve precise rotational positioning of the catheter 100. With reference to Figure 5e'', the passageway-forming catheter 100 has a circular radiographically visible marking 124 on one side and a disk or dot shaped radiographically

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marking 126 on the other side, directly opposite the circular marking 124. In this manner, precise rotational positioning of the catheter 100 may be achieved by causing the disk or dot shaped marking 126 to become  
5 positioned within the circular marking 124, as viewed on the screen 120. This is illustrated in the lower side box of Figure 5e'.

Yet another type of radiographically visible marking which may be utilized to attain precise rotational  
10 positioning of the catheter 100 is shown in Figure 5e'''. With reference to Figure 5e''', there is provided a catheter 100 having two (2) radiolucent apertures 128a, 128b of substantially equivalent size, formed directly opposite one another, on opposite sides of the catheter  
15 100. In this manner, precise rotational positioning of the catheter 100 may be achieved by rotating the catheter 100 until the first and second radiolucent apertures 128a and 128b become directly aligned with one another such that they appear as a single opening when viewed upon the  
20 screen 120, as illustrated in the side box of Figure 5e'''.

Figure 5f-5f' show the manner in which an ultrasonically visible marking 130 formed upon the passageway-forming catheter 100 may be utilized in  
25 conjunction with an extracorporeally positioned ultrasound imaging transducer 132 to effect precise rotational orientation of the catheter 100. As shown, the ultrasonically visible marker 130 is formed at a specific location on the catheter 100, such specific  
30 location having a known relationship to the site and direction in which the tissue-penetrating element 102 will pass from the catheter 100. The extracorporeal ultrasound imaging transducer 132 is positioned on the body so as to image both the blood vessel BV<sub>1</sub> wherein the  
35 passageway-forming catheter 100 is positioned and the target (e.g., second blood vessel, tissue mass, or other target location) into which the tissue-penetrating

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element 102 of the catheter 100 is to be passed. Thereafter, the catheter 100 is rotated until the ultrasonically visible marking 130 is clearly and completely imaged by the transducer 132. Such positioning of the ultrasonically visible marker 130 serves to establish that the catheter has been placed in its proper rotational orientation to cause the tissue-penetrating element to pass into the target T.

Figures 5g-5g'' illustrate the manner in which passive markers on the passageway-forming catheter 100 are utilized in conjunction with a magnetic resonance imaging (MRI) system, to effect precise longitudinal and rotational positioning of the catheter 100 as well as for determination of the distance between the blood vessel in which the catheter 100 is located and the target T, so as to provide a means for determining the distance which must be traveled by the tissue-penetrating element 102 in order to form the desired passageway between the blood vessel BV<sub>1</sub> and target T. In this embodiment, the body of the catheter 100 is formed of material which is visible by MRI. Additionally, a discrete MRI marker 134 is formed on the body of the catheter, at a specific location. The marker may comprise an induction coil 134a or a small mass of matter 134b which differs from the material of which the catheter body 100 is formed so as to be specifically visible on MRI.

With specific reference to Figure 5g', the induction coil 134a is positioned on or within the wall of the catheter 100 at a specific location, and is connected by wires 135 which extend through the catheter to an exterior location where they may be connected to a suitable current source, oscilloscope and/or other monitoring system whereby current, phase and amplitude of the electromagnetic field within the coil 134a may be monitored. In this manner, movement of the catheter 100 within the MRI scanner 135 will cause the location of the coil 134a to be altered within the variable but known

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magnetic field created by the MRI system. In this manner, each movement of the catheter 100 within the MRI field will result in a change in current, phase and amplitude. The current phase and amplitude information  
5 received from the coil 134a may then be utilized to determine the precise location of the coil 134a relative to the target T. Moreover, if the coil 134a becomes located out of the specific plane which is being imaged by the MRI scanner 135, such will indicate the catheter  
10 100 has been longitudinally moved out of the desired plane. In this manner, the coil 134a may be utilized for precise longitudinal, and rotational orientation of the catheter 100. Moreover, the information received from the coil 134a may be utilized to determine the exact  
15 distance between the coil 134a and the target T thereby providing information which will enable the operator to control the tissue-penetrating element 102 in a manner consistent with the length of the passageway 10 to be formed.

20 With specific reference to Figure 5g'', an alternative MRI marker 134b comprises a discrete mass of material which differs from the material of the catheter body 100, and which is visible on MRI. In this manner, the MRI-visible marker 134b may be precisely viewed on  
25 the MRI image, and may be utilized to visually adjust the longitudinal or rotational orientation and positioning of the catheter 100 relative to the target T. Moreover, the viewed distance between the marker 134b and the target T may be utilized to enable the operator to control the  
30 passage of the tissue-penetrating element 102 to create a passageway 10 of the desired length between the blood vessel BV<sub>1</sub> within which the catheter 100 is located and the target T.

35 Examples of specific types of "active" imaging apparatus which may be associated with, mounted upon or incorporated into the passageway-forming catheter 100 to

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facilitate precise rotational orientation of the catheter 100 within a blood vessel, are shown in Figures 5h-5l.

With reference to Figure 5h, one type of active imaging apparatus which may be associated with, mounted upon or incorporated into the passageway-forming catheter 100 is a Doppler apparatus 136, such as that which is incorporated in a commercially available devices known as the Smart Needle, Cardiovascular Dynamics, Inc., Sunnyvale, California.

With reference to Figure 5h, the Doppler apparatus 136 is mounted upon or within the catheter 100 and is aimed or directed in a lateral direction (e.g., perpendicular to the longitudinal axis of the catheter 100). The Doppler apparatus 136 is useable to locate and discern a flow of fluid or other matter within the target T. Thus, the embodiment shown in Figure 5h is usable when target T comprises a blood vessel or other anatomical structure wherein fluid or other matter is flowing. The amplitude of the signal provided by the Doppler apparatus 136 and other information discernable therefrom enables the operator to a) longitudinally position the catheter such that the Doppler apparatus 136 is imaging the desired flow characteristics with in the target T (e.g, downstream of an obstruction and an artery), b) rotationally orient the catheter such that the amplitude of the Doppler signal is peaked so as to indicate that the Doppler apparatus 136 is precisely aimed at the center of flow within the target T (e.g., the center of the lumen in a blood vessel) and c) determine the distance between the Doppler apparatus 136 and the center of flow within the target T. Such determination of the distance between the Doppler apparatus 136 and the center of flow (e.g., lumen center) within the target T will enable the operator to control the tissue-penetrating element 102 such that the tissue-penetrating element 102 will pass or extend only the desired distance from the catheter 100, thereby forming

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a passageway 10 into the center of flow (e.g., lumen) of the target but not traveling too far as could puncture or perforate the contralateral side of the target T.

After the catheter 100 has been positioned in the first blood vessel BV<sub>1</sub>, the Doppler apparatus 136 will be activated and the catheter 100 will be moved longitudinally and/or rotated until the Doppler signal is indicative of the desired flow within the imaged portion of the target T and such that the amplitude of the Doppler signal has peaked, thereby indicating that the Doppler apparatus 136 has been directly aligned with the target T. Thereafter, the frequency output of the Doppler apparatus 136 may be varied and the frequency which produces the peak amplitude response will indicate the distance from the Doppler apparatus 136 to the target T. In this embodiment, the target T must be a blood vessel or other anatomical structure wherein flow of matter is present, so as to be discerned by sonic (e.g., Doppler) means.

Figure 5i shows an embodiment wherein an intravascular ultrasound imaging apparatus 138 is positioned on the passageway forming catheter 100 at a specific location on one side of the catheter 100. Such specific location of the ultrasound imaging apparatus 100 is preferably a known linear distance and known rotational distance away from the location at which the tissue-penetrating element 102 will pass out of the catheter 100. After the catheter 100 has been positioned within a first blood vessel BV<sub>1</sub>, the catheter 100 may be rotated until the target T (e.g., blood vessel, pulsating tissue, or other target locations visible by ultrasound imaging) is in direct alignment, and is directly imaged by, the ultrasound apparatus 138, thereby indicating that the catheter 100 has been longitudinally and rotationally oriented to cause the tissue-penetrating element 102 to pass through the wall of the first blood vessel BV<sub>1</sub> and into the target T, as intended.

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Figure 5j illustrates the manner in which a first transmitter/receiver wire 140a and a second transmitter wire 140b may be utilized to accomplish precise rotational orientation of the passageway-forming catheter 100. As shown, the first transmitter or receiver wire 140a is positioned on or within the wall of the passageway-forming catheter 100 at a specific location, on one side of the catheter 100. The location of this first transmitter or receiver wire 140a is preferably immediately adjacent the location at which the tissue-penetrating element 102 will exit the catheter 100. A second transmitter or receiver wire 140b is positioned within the target T (e.g., second blood vessel, target tissue or other location into which the tissue-penetrating element of the passageway-forming catheter 100 is to be passed). After the catheter 100 has been advanced into the first blood vessel BV<sub>1</sub>, the catheter will be rotated while a signal is emitted from one transmitter or receiver wire 140a, 140b such that such signal may be received by the other transmitter or receiver wire 140a, 140b. In this manner, the catheter may continue to be rotated until the amplitude of the signal received by the receiving transmitter/receiver wire 140a, 140b is peaked, thereby indicating that the first transmitter/receiver wire 140a and second transmitter receiver wire 140b are at their closest point, thereby indicating that the catheter 100 has been positioned in its desired rotational orientation within the first blood vessel BV<sub>1</sub>. Additionally, one or both of the receiver wires 140a, 140b may be positioned in the respective blood vessel BV<sub>1</sub> and/or target area T to effect the desired longitudinal positioning of the catheter 100 within the blood vessel BV<sub>1</sub>, when the monitored signal between the wires 140a, 140b so indicates.

Figure 5k shows alternative arrangement wherein induction coil 142 is formed upon or within the wall of

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the passageway-forming catheter 100 at a specific location which corresponds to the site from which the tissue-penetrating element 102 will exit the catheter 100. A transmitter wire 144 is positioned within the target T (e.g., second blood vessel, target tissue or other location into which the tissue-penetrating element 102 of the catheter 100 is intended to pass) the transmitter wire 144 is energized so as to emit an electromagnetic signal and the induction coil 142 is also energized. Thereafter, the catheter 100 is rotated until the phase and amplitude of the signal within the induction coil 142 indicates that the induction coil 142 is at its closest point to the transmitter wire 100, thereby confirming that the catheter 100 has been placed in its appropriate rotational orientation to cause the tissue-penetrating element 102 to pass from the catheter 100, through the wall of the first BV<sub>1</sub>, and into the target T.

Figure 51 illustrates the manner in which first and second magnets 146a-146b may be utilized to effect precise rotational orientation of the passageway-forming catheter 100. The first magnet 146a is positioned on or within the wall of the passageway-forming catheter 100 at a specific location which corresponds to the site from which the tissue-penetrating element 102 will exit the catheter 100. The second magnet 146b is positioned on a second catheter 148 which is inserted into the target T (e.g., second blood vessel, target tissue or other location into which the tissue-penetrating element 102 is to be passed). The passageway-forming catheter 100 is then rotated, or is allowed to auto rotate) until the first magnet 146a and second magnet 146b are in alignment with and as close as possible to one another, thereby indicating that the passageway-forming catheter 100 has been placed in its correct rotational orientation to cause the tissue-penetrating element 102 to pass through

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the wall of the first blood vessel BV<sub>1</sub> and into the target T.

**B. Devices of the Present Invention**

Figures 6 through 12 show devices of the present invention which are useable to form extravascular passageways 10 in accordance with the present invention, or to otherwise modify or equip such passageways 10. It is to be appreciated that the showings of Figures 6-12 and the detailed descriptions set forth herebelow are intended to describe and illustrate certain examples and presently preferred embodiments of the devices only, and are not intended to exhaustively list and describe all possible devices or embodiments in which the present invention may take physical form.

**i. Exit Schemes For Facilitating Passage of the Tissue-Penetrating Element Out of the Catheter Body**

Figures 6a-6i show examples of arrangements and apparatus whereby a tissue-penetrating element 102 useable to initially form an extravascular passageway 10 of the of the present invention, may be passed out of a passageway-forming catheter 100 positioned within the lumen of a blood vessel such that the tissue-penetrating element 102 will pass through the wall of the blood vessel in which the catheter 100 is positioned, so as to create the desired extravascular passageway 10.

The detailed description of Figures 6a-6i set forth herebelow makes reference to various types of tissue-penetrating elements 102. The term "tissue-penetrating element" as used herein is intended to encompass all possible types of elongate members which may be utilized to penetrate tissue, devices or apparatus which may be utilized to penetrate tissue, or flows of energy (e.g., heat, laser beam, etc.) which may be used to penetrate tissue. Thus, when it is stated that the tissue-penetrating element 102 is "passed" out of the catheter 100, such statement shall not necessarily imply the

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passage of a solid element from the catheter body, but may also include the operation of a tissue-penetrating apparatus or the passage of a flow of energy (e.g., heat, laser) from the catheter body in a manner and direction which will create the desired extravascular passageway 10. Furthermore, it shall be appreciated that the showings of Figures 6a-6i and the description provided in conjunction with such figures is not intended to describe or illustrate all possible arrangements or apparatus by which the tissue-penetrating elements 102 may be passed out of the passageway-forming catheters 100 of the present invention. Additionally, the following detailed description makes reference to some tissue-penetrating elements 102 which comprise a "pre-bent resilient member". The term "pre-bent resilient member" shall mean a member which when unconstrained will assume a curved or curvilinear configuration but which is sufficiently flexible to be withdrawn into and constrained by a lumen of the catheter device 100 without causing plastic deformation of the member. Examples of materials which may be utilized to form the pre-bent resilient members useable to form some of the tissue-penetrating elements 102 of the present invention include materials which are resilient, elastic or superelastic at body temperature and within the range of other temperatures under which the device will be utilized. Examples of these materials include some stainless steels, some plastics, and certain superelastic metal alloys and polymers such as nickel titanium alloys.

Figure 6a shows an embodiment of the passageway-forming catheter 100a wherein a lumen 112a extends longitudinally through the catheter 100a and terminates distally in a distal end aperture 114. The tissue-penetrating element 102 comprises a pre-bent, resilient member, as defined hereabove. When retracted within the lumen 112, this embodiment of the tissue-penetrating element 102 assumes a substantially straight, non-bent or

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minimally bent configuration in conformance to the surrounding wall of the catheter 100a. However, when the tissue-penetrating element 102 is advanced out of the outlet aperture 114a in the distal end of the catheter 100a, the tissue-penetrating element 102 will assume its pre-bent configuration such that the distal end of the tissue-penetrating element 102 will penetrate through the wall of the blood vessel wherein the catheter 100a is positioned. It is to be appreciated with respect to this embodiment, and all other embodiments of the invention herein described, that the tissue-penetrating element 102 may be configured to form any desired shape and size of passageway 10. Thus, in embodiments wherein the tissue-penetrating element 102 comprises a pre-bent resilient member, the pre-bent configuration of the tissue-penetrating element may be continuous curvilinear, partially straight and partially curvilinear, multicurvate, or any other pre-bent configuration which is suitable to form the initial extravascular passageway 10 of the desired size and shape. Furthermore, as described in more detail herebelow, various passageway modifying devices may be utilized to debulk, enlarge, dilate or otherwise modify the size and/or shape of the passageway such that the resultant final shape of the passageway 10 may differ substantially from that which is initially created by the first penetration of the tissue-penetrating element 102.

Figure 6b shows a passageway-forming catheter device 100b having a lumen 112 extending longitudinally therethrough and terminating distally in a side wall outlet aperture 114b. A deflector surface 115 is formed within the lumen 112b, between the side wall aperture 114b, and the contralateral surface of the lumen 112b. A tissue-penetrating element 102 formed of pliable material is of a substantially straight configuration when retracted within the lumen 112b. However, when advanced in the distal direction, the distal end of this

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tissue-penetrating element 102 will be deflected by the deflector surface 115, and will exit the body of the catheter 100b through side wall aperture 114b. In this manner, the tissue-penetrating element may be caused to  
5 exit the body of the catheter 100b in a lateral direction relative to the longitudinal axis LA of the catheter 100b.

Figure 6c shows a catheter device 100c having a lumen 112c extending longitudinally therethrough and  
10 terminating distally in a side wall outlet aperture 114c. The tissue-penetrating element 102 may be a pre-bent resilient member and is of a substantially straight configuration when fully retracted into the lumen 112c of the catheter 100c. However, when this tissue-penetrating  
15 element 102 is advanced in the distal direction, the distal end of such pre-bent resilient member 102 will self-locate and pass out of the outlet aperture 114c due to its inherent tendency to seek its pre-bent configuration, without any need for abutment against or  
20 deflection from any surface of the wall of the lumen 112c.

Figures 6d and 6d' show a catheter device 100d which has a lumen 112d extending longitudinally therethrough and terminating in a distal end outlet aperture 114d. An  
25 anvil member 180 is mounted a spaced distance forward of the distal end of the catheter 100d, and is attached to the catheter by way of integrally formed struts 182. The anvil member 180 has blunt distal surface 184, and a deflector surface 186 formed on the proximal side  
30 thereof, in direct alignment with the distal end outlet aperture 114d of the lumen 112d of the catheter 100d. The tissue-penetrating element 102 in this embodiment may comprise either a pliable member or resilient, pre-bent member which assumes a substantially straight or  
35 minimally bent configuration which conforms to and is retractable into the lumen 114d of the catheter, as shown. However, when the puncturing element 102 is

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advanced out of the distal end opening 114d of the catheter, the distal tip of the tissue-penetrating element 102 will abut against the deflector surface 186 of the anvil member 180, and will be thereby deflected, guided or caused to bend or curve in the lateral direction, such that the tissue-penetrating element will pass through the wall of the blood vessel BV, as shown.

Preferably, the deflector surface 186 of the anvil member 180 is not continuous with the inner surface of the lumen 112d of the catheter 100d.

Figure 6e shows another embodiment of the catheter device 100e wherein the catheter device 100e comprises a retractable outer catheter sheath 190, and an elongate inner member 192 having a pre-bent, resilient tube 194 formed within or mounted within the distal portion thereof. The elongate inner member 192 has a blunt distal tip 196 and an elongate side opening 198 formed therein, such that when the outer catheter sheath 190 is retracted in the proximal direction, the pre-bent resilient tubular member 194 will spring outwardly to its pre-bent, laterally-curved configuration, as shown. The tissue-penetrating element 102 of this embodiment may be a pliable member or a pre-bent resilient member which will assume a pre-bent configuration when advanced out of the distal end opening 114e formed in the distal end of the inner tube member 194. In this manner, the pre-bent tube member 194 may form a first angle,  $A_1$  when the catheter sheath 190 is retracted in the proximal direction, and the pre-bent, resilient tissue penetrating element 102 may form an additional second angle  $A_2$  when it is advanced out of the distal end opening 114e of the pre-bent tube member 194, such that the first angle  $A_1$  and second angle  $A_2$  will combine to form a resultant third angle  $A_3$  between the direction in which the distal tip of the tissue-penetrating element 102 is aimed and the longitudinal axis LA of the catheter 100e. As explained in detail hereabove, the angle  $A_3$  between the direction

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of the distal tip of the tissue-penetrating element 102 and the longitudinal axis LA of the catheter 100e does not necessarily dictate or define the precise angle at which the passageway 10 will be formed by the tissue-penetrating element 102. Indeed, the tissue-penetrating element 102 may be of any suitable configuration including a continuously curvilinear configuration which will create a continuously curvilinear passageway.

Figure 6f shows another embodiment of the catheter device 100f, wherein the catheter device 100f comprises a tubular outer sheath 202 which is retractable in the proximal direction, and an elongate inner member 204 having a blunt distal tip 206 and a side opening 208 formed therein. The tissue-penetrating element 102 is preferably a pre-bent resilient member mounted within the elongate member 104, immediately adjacent the side opening 208 such that, when the outer catheter sheath 202 is advanced so as to cover the side opening 208, the tissue-penetrating element 102 will assume a substantially straight or minimally bent configuration so as to conform to, and be contained within, the inner lumen 112f of the catheter device 100f. However, when the outer sheath 202 is withdrawn in the proximal direction so as to expose the side opening 208, the tissue-penetrating element 102 will spring outwardly to its pre-bent configuration such that the distal end of the tissue-penetrating element will be directed toward, or will be placed in immediate contact with, the wall of the blood vessel BV within which the catheter device 100f is inserted. In at least some embodiments, the tissue-penetrating element may thereafter be advanced in the distal direction so as to penetrate through the wall of the blood vessel and through any extravascular tissue required to form the extravascular passageway 10 in accordance with the present invention.

Figure 6g shows yet another embodiment of a passageway-forming catheter device 100g comprising a

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tubular catheter body having a hollow lumen 112g extending longitudinally therethrough and opening distally through a distal end opening 114g. The distal end of the body of the catheter 100g is bendable in a lateral direction, as shown in the dotted lines of Figure 6g. Such bending of the distal end of the catheter device 100g in the lateral direction, will cause the outlet aperture 114g to become directed toward the wall of the blood vessel within which the catheter device 100g is positioned, such that subsequent advancement of the tissue-penetrating element 102 out of the distal end opening 114g of the catheter device 100g will cause the tissue-penetrating element 102 to contact and pass through the wall of the blood vessel BV within which the catheter device 100g is positioned. The bendable distal end of the catheter 100g may be caused to transition from its straight configuration to its curved or bent configuration by the presence of a shape memory alloy, a pull wire, opposing electromagnetic coils or any other suitable mechanism, apparatus or material known in the art for causing the tip of a catheter to bend.

Figure 6h shows yet another embodiment of a passageway-forming catheter device 100h comprising a tubular catheter 100h having a tissue-penetrating element 102 passable therefrom. An inflatable balloon 210 is formed on one side of the catheter device 100h, opposite the location at which the extra-vascular passageway 10 is to be formed in the wall of the blood vessel BV. Inflation of the balloon 210 prior to or during advancement of the tissue-penetrating element 102 will a) deter or prevent the catheter 100h from recoiling and pressing against the contralateral wall of the blood vessel BV as the tissue-penetrating element 102 is advanced through the wall of the blood vessel BV, and b) may operate to stabilize and hold the distal portion of the catheter device 100h in a substantially fixed position within the lumen of the blood vessel BV, so as

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to permit the application of an enhanced force or pressure upon the tissue-penetrating element 102 as it is advanced or otherwise passed through the wall of the blood vessel BV. In the embodiment shown in Figure 6h, the catheter device has a distal end outlet opening 114h and the tissue-penetrating element 102 is a pre-bent resilient member which will assume a laterally bent or curved configuration as it exits the distal end opening 114h. It will be appreciated, however, that the side balloon 210 shown in Figure 6h may be incorporated and used in conjunction with any of the types of catheters show in Figures 6a-6i, including those wherein the tissue-penetrating element exits through a side-outlet aperture formed in the side wall of the catheter device 100h.

Figure 6i shows yet another embodiment of a passageway-forming catheter device 100i comprising an elongate, flexible, tubular catheter body having a hollow lumen 114i extending longitudinally therethrough and a blunt tip member 212 rotatably mounted on the distal end of the tubular catheter body. The distal tip member 212 has a curved lumen 214 extending therethrough, the proximal end of which is in alignment with the lumen 114i of the catheter 100i. and the distal end of which terminates in a side outlet aperture 114i formed on one side of the distal tip member 112. The tissue-penetrating element 102 in this embodiment may comprise a pliable member or a resilient pre-bent member. In either instance, the tissue-penetrating element 102 may be initially advanced to an intermediate position wherein the distal tip of the tissue-penetrating element is positioned within the curved lumen 214 of the distal tip member 212. With the tissue-penetrating element 102 in such intermediate position, the tissue-penetrating element 102 may be rotated. Such rotation of the tissue-penetrating element 102 will, due to its frictional engagement within the curved lumen 214 of the distal tip

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member 121, cause the distal tip member 212 to concurrently rotate. In this manner, partial advancement and rotation of the tissue penetrating element 102 may be utilized as a means for rotatably moving the distal tip member 212 to adjust the rotational orientation of the side outlet aperture 114i so as to direct the tissue-penetrating element in the desired lateral direction to form the extravascular passageway 10 of the present invention at the desired location. In this manner, further advancement of the tissue-penetrating 102 out of the side outlet aperture 114i, after the desired rotational orientation of the distal tip member 212 has been achieved, will cause the tissue-penetrating element to form the desired extravascular passageway 10 through the wall of the blood vessel BV within which the catheter device 100i is positioned.

ii. Types of Tissue-Penetrating Elements Which May Be Incorporated Into the Passageway-Forming Catheter

The following Figures 7a-7m and the accompanying detailed description set forth herebelow are intended to describe and illustrate some types of tissue-penetrating elements 102 which may be utilized in accordance with the present invention. It is to be appreciated and understood that the specific types of tissue-penetrating elements 102 described herebelow and shown in Figures 7a-7m are not intended to exhaustively list and explain all possible types of tissue-penetrating elements 102 which may be useable but, rather, are intended to provide examples of the types of tissue-penetrating elements 102 which may be utilized. As explained hereabove, the term "tissue-penetrating element" is not limited to solid members but may also include various devices, apparatus, or flows of energy. Furthermore, the term "resilient, pre-bent member" shall be interpreted in accordance with the definition of such term set forth hereabove.

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With reference to Figures 7a-7m, there are shown various types of tissue-penetrating elements 102 which may be incorporated into the passageway-forming catheter 100 of the present invention. These tissue-penetrating elements 102 are designed to pass out of a flexible catheter body and to penetrate through the wall of the blood vessel within which the catheter 100 is located, and to adjacent extravascular tissue, as necessary, to form the desired extravascular passageway 10 of the present invention.

Figures 7a and 7a' show a first embodiment of a tissue-penetrating element 102a. This embodiment of the tissue penetrating element 102a comprises an elongate, pliable needle formed of a pliable material such as polyimide tubing of the type available commercially from MicroLumen, Inc., Tampa, Florida, and having a sharpened, beveled distal tip 300 formed thereon. An optional lumen 302 may extend longitudinally through the penetrating element 102a. A pre-bent, resilient member 304 is positioned longitudinally within the tissue-penetrating element 102a, or alternatively a pull wire.

When the element 102a is retracted within the lumen of the passageway-forming catheter 100, the resilient spine member 304a will be caused to assume a substantially straight or minimally bent configuration which conforms to the configuration of the catheter lumen and allows the tissue-penetrating element 102a to be fully retracted within the catheter lumen. However, when the tissue-penetrating element is exposed or advanced out of the passageway-forming catheter 100, a distal portion of the pre-bent spine member 304 will bend or curve in a lateral direction, thereby causing the entire, pliable tissue-penetrating element 102a to assume such laterally bent and curved configuration, as designated by the phantom lines on Figure 7a. In this manner, the pre-bent resilient spine member 304 will cause the pliable or flexible body of the tissue-penetrating element to assume

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the desired laterally bent or curved configuration. In some instances, this arrangement may also allow the pliable body of the tissue-penetrating element 102a to be rotated or spun around the pre-bent resilient spine member 304a to facilitate or enhance advancement of the tissue-penetrating element through the blood vessel wall or adjacent tissue.

Figure 7b shows another embodiment of a tissue-penetrating element 102b which comprises a pliable elongate proximal shaft 306 having a rigid, sharpened distal tip member 308 mounted upon, or otherwise joined to the distal end of the proximal shaft 306. In this embodiment, the proximal shaft 306 of the tissue-penetrating element 102b is sufficiently pliable and bendable to navigate tortuous anatomical curves or curves within the lumen of a catheter, while the rigid distal tip portion 308 is formed of rigid material, such as stainless steel, so as to maintain a substantially sharp distal tip 310 which will penetrate and pass through the blood vessel wall and desired extravascular tissue, to form the extravascular passageway 10 in accordance with the present invention.

Figure 7c shows another embodiment of a tissue-penetrating element 102c which comprises an elongate solid or hollow needle having a sharpened distal tip 312, and formed of a pre-bent resilient material such as a superelastic nickel titanium alloy or other metal alloy which exhibits resilient, elastic or superelastic properties within the range of temperatures which the tissue-penetrating element 102c will encounter during normal use. This embodiment of the tissue-penetrating element 102c, being formed of pre-bent resilient material, will assume a substantially straight or minimally bent configuration when retracted into the lumen 112 of the passageway-forming catheter 100, such that the entire tissue-penetrating 102c may be retracted into the lumen 112. However, when the tissue-penetrating

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element 102c is advanced out of the outlet aperture 114c in the catheter 100, the tissue-penetrating element 102c will assume its pre-bent configuration so as to become curved or bent in the lateral direction at an angle A relative to the longitudinal axis LA of the catheter, thereby facilitating advancement of the distal portion of the tissue-penetrating element 102c through the blood vessel wall and through any adjacent tissue to form the desired extravascular passageway 10 in accordance with the present invention.

Figure 7d shows yet another embodiment of a tissue penetrating element 102d which comprises a hollow needle having a sharpened (e.g., beveled) distal tip 314 and a guide wire passage lumen 316 of extending longitudinally therethrough. It will be appreciated that this hollow needle may be formed of either pre-bent, resilient material or pliable material, in accordance with the various tissue-penetrating element exit schemes illustrated in Figures 6a-6i and described in detail hereabove. The embodiment of the puncturing element 102d shown in Figure 7d has the advantage of permitting a guide wire GW to be advanced through the guide wire passage lumen 316. In this manner, the guide wire GW may be periodically advanced in the distal direction or may be placed under continuous distally directed pressure such that, when the sharpened distal tip 314 of the tissue-penetrating element 102d enters the lumen of another blood vessel or another hollow cavity, the guide wire GW will rapidly advance in the distal direction, thereby signaling that the sharpened distal tip 314 of the tissue-penetrating element 102d has entered such blood vessel lumen or hollow cavity. Thus, this embodiment of the penetrating element 102d is particularly useable in the revascularization methods of the present invention wherein an extravascular passageway 10 is formed between two blood vessels, or in other extravascular procedures of the present invention wherein

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the extravascular passageway 10 is to be formed between a blood vessel and a target T which comprises another blood vessel or other hollow cavity of the body. Distally directed pressure on the guide wire GW may be applied manually or by way of a pressure-exerting safety apparatus of the type shown in Figures 10c', 10c'' and 10c''' and described fully herebelow.

Figure 7e shows yet another embodiment of a tissue-penetrating element 102e comprising a solid needle having a sharpened (e.g., beveled) distal tip 318. This embodiment of the puncturing element 102e may be formed of a continuous solid elongate member, such as a wire, as illustrated in Figure 7e'. Alternatively, as illustrated in Figure 7e'', this embodiment of the tissue-penetrating element may comprise an outer tubular member 102e'' having a hollow lumen 114e'' extending longitudinally therethrough, and a removable solid stylet member 320 inserted coaxially within the hollow lumen 114e'' of the penetrating element 102e'' such that the tubular penetrating element 102e'' in combination with the solid stylet member 320 will essentially form a solid needle structure similar to the solid elongate puncturing element 102e' shown in Figure 7e'.

Figure 7f shows yet another embodiment of a tissue-penetrating element 102f which is made up of the combination of an elongate solid or tubular member 322 having a sharpened trocar tip 324 formed on the distal end thereof, and a surrounding, longitudinally-advanceable outer sheath 326. The distal portion of the outer sheath 326 may be tapered, not shown, such that it may pass over and shield the sharpened trocar tip 324 of the elongate member 322. However, when being advanced through the blood vessel wall or other tissue, the sharpened trocar tip 324 will emerge out of the distal end opening of the outer sheath 326 so as to penetrate and advance through the blood vessel wall and/or other tissue. When the trocar tip has passed into another

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blood vessel lumen or other hollow body cavity, the outer sheath 326 may be advanced in response to intermittent or continuous distally directed pressure applied to the outer sheath 326. Such distally directed pressure may be applied manually or by way of a continuous pressure-exerting safety device of the type shown in Figures 10c', 10c'' and 10c''', as described fully herebelow.

Figure 7g shows yet another embodiment of a tissue-penetrating element 102g which comprises an elongate tubular member 328 having an energy emitting distal tip 330 formed on the distal end thereof. One or more energy transmission wires or members 332 may extend through the tubular member 328 and will be connected to the energy-emitting distal tip 330 so as to deliver the desired form of energy to the distal tip 330. In this manner, the energy-emitting distal tip may emit any suitable type of energy which will ablate, sever or facilitate advancement of the member 328 through a blood vessel and other extravascular tissue, in accordance with the methodology of the present invention. Examples of the types of energy which may be emitted from the energy-emitting distal tip 330 include heat (e.g., electrical resistance heat or laser heat to form a "hot tip"), monopolar electrocautery, bipolar electrocautery, ultrasound, etc.

Figure 7h shows yet another embodiment of a tissue-penetrating element 102h comprising an elongate flexible catheter 100 having a lumen 112 extending longitudinally therethrough and a rotatable passageway-forming tip 336 mounted on the distal end thereof. A rotatable drive member 338 extends longitudinally through the lumen 112 of the catheter 100, and operates to rotate the distal tip 336 when it is desired to advance the tissue-penetrating element 102h through the wall of a blood vessel or other tissue. The rotating distal tip 336 may be of any suitable configuration which, when rotated, will form a tunnel or passageway through tissue of the desired configuration. In this regard, the outer surface

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of the rotatable tip 336 may be provided with a sharpened spiral blade or threaded member 337 or other suitable tissue-cutting or dilating apparatus to facilitate the rotational boring, cutting or dilation of tissue, desired of the rotatable tip 336.

Figure 7i shows yet another embodiment of a tissue-penetrating element 102i. In this embodiment, the tissue-penetrating element 102i comprises a beam of pulsed or continuous laser light which is projected out of an aperture or lens-covered port 114i formed in the catheter 100. A laser-transmitting element 340 such as a fiber optic extends longitudinally through the lumen 112 of the catheter 100, and terminates proximal to and in alignment with a reflective surface 341, such as a mirror, from which the laser light emanating from the distal end of the laser transmitting member 340 will be reflected out of the side aperture or port 114i. Thus, in this particular embodiment, the tissue-penetrating element 120i is not formed of solid matter or deployable tissue penetrating apparatus, but rather, comprises a pulsed or continuous beam of laser light capable of vaporizing or ablating the blood vessel wall and other extravascular tissue to form the desired extravascular passageway 10 of the present invention.

It will be appreciated that this embodiment of the tissue-penetrating element 102i may be modified in various ways. For example, in place of the reflective surface 341, a continuous energy guide (e.g., fiber optic) may extend through the catheter body and terminate in an outlet port or lens located on the side wall of the catheter, such that the flow of energy (e.g., laser light) will pass outward in the lateral direction from the catheter. Alternatively, an energy-emitting apparatus may be mounted on or within the side wall of the catheter so as to emit the desired flow of energy in a lateral outward direction from the catheter. Moreover, the embodiment specifically shown in Figure 7i and the

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above-mentioned variations thereof shall not be limited to laser energy, but may utilize any suitable flow of energy including heat, ultrasound, laser light, etc.

Figure 7j shows yet another embodiment of tissue-penetrating element 102j which may be incorporated into the passageway-forming catheters 100 of the present invention. In this embodiment, the tissue-penetrating element 102j comprises an elongate laser-transmitting member through which laser energy may be passed such that the laser energy will emanate out of the distal end 343 of the elongate laser-transmitting member 102j. The elongate laser-transmitting member 102j may be pre-bent such that if it is passed out of a distal end opening 114 in a catheter 100, it will automatically bend or curve in a lateral direction so as to contact the wall of the blood vessel BV within which the catheter 100 is located, to allow laser energy emanating from the distal end 343 of the laser-transmitting member 102j to form the desired extravascular passageway 10 in the wall of the blood vessel and other extravascular tissue. Alternatively, it will be appreciated that various other exits schemes may be utilized for the laser-transmitting member 102j, such as sidewall apertures formed in the catheter 100, in accordance with the suitable exits schemes for all tissue-penetrating elements 102 as illustrated in Figure 6a-6i and described fully hereabove.

Figure 7k shows yet another alternative embodiment of a tissue-penetrating element 102k usable in the passageway-forming catheters 100 of the present invention. The tissue-penetrating element 102k shown in Figure 7k comprises an elongate hollow needle having a lumen 316 extending longitudinally therethrough and having a sharpened distal tip. A vacuum source (e.g., suction) 344 is attached to the proximal end of the lumen 316 of the tissue penetrating element 102k so as to draw or pull tissue into the lumen 316 as the distal end of the tissue-penetrating element is being advanced through

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the wall of the blood vessel BV or other tissue through which the extravascular passageway 10 of the present invention is to be formed. An optional sealing cuff 317, which may comprise an inflatable annular balloon mounted about the exterior of the tissue-penetrating element 102k a spaced distance from the sharpened distal tip thereof, may be positioned in abutment with the wall of the blood vessel BV so as to form a seal which will prevent the suction applied to the lumen 316 from the leaking outwardly or aspirating blood from the lumen of the blood vessel BV. In this manner, the optional sealing cuff 317 may facilitate drawing or aspiration of the tissue of the blood vessel wall BV or other extravascular tissue into the distal end of the lumen 316 as the tissue-penetrating element 102k is advanced through the tissue of the blood vessel wall or other extravascular tissue.

Yet another embodiment of a tissue-penetrating element 102l useable in the passageway-forming catheters 100 of the present invention, is shown in Figure 71. With reference to Figure 71, there is provided a tissue-penetrating element 102l formed by the combination of a standard tissue-penetrating element 102 such as a solid or hollow needle having a sharpened distal tip, and a surrounding tubular sheath 346 having a resilient, pre-bent distal portion 347 and a hollow lumen 349 extending longitudinally therethrough. The sheath 346 having the tissue-penetrating element 102 mounted therewithin is advanced through the lumen 112 of the catheter 100. When the distal portion 347 of the sheath 346 is advanced out of the distal end opening 114 of the catheter 100, the pre-bent distal portion 347 of the sheath will automatically curve or bend in a lateral direction, as illustrated by the dotted lines on Figure 71. Thereafter, the pliable or pre-bent tissue-penetrating element 102 will be advanced through the lumen 349 of the sheath 346, and through the wall of the blood vessel BV or other extravascular tissue to form the desired

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extravascular passageway 10 in accordance with the present invention. Optionally, a vacuum source 345 may be connected to the proximal end of the lumen 349 of the sheath 346 to draw the wall of the blood vessel BV into contact with the distal end of the distal portion 347 of the sheath 346, thereby facilitating efficient advancement and penetration of the tissue-penetrating element 102 through the blood vessel wall or other tissue.

Yet another embodiment of a tissue penetrating element 102m is shown in Figure 7m. With reference to Figure 7m, there is provided a catheter 100 having a side wall opening 114 formed therein and a hollow lumen 112 extending longitudinally therethrough, and terminating at side wall opening 114. A tissue-penetrating element 102, such as a sharp-tip hollow or solid needle, is advanceable through the lumen 112 of the catheter 100 and out of the side opening 114. A vacuum source 350 (e.g., suction) is attached to the proximal end of the lumen 112 and suction is applied, to draw the wall of the blood vessel BV downwardly and into contact with the side aperture 114, as shown in Figure 7m. Such suction-induced contact of the wall of the blood vessel BV with the side aperture 114 facilitates efficient advancement and penetration of the tissue-penetrating element 102 through the wall of the blood vessel BV, to create the desired extravascular passageway 10 in accordance with the present invention. Also, this suction attachment helps to hold the tissue which is being penetrated, in a taught state, thereby facilitating penetration of such tissue.

### iii. Passageway-Modifying Apparatus

Figures 8a-8h and the detailed description thereof set forth herebelow show various types of apparatus which may be utilized to treat, enlarge, debulk, dilate, line, coat or otherwise modify the extravascular passageway 10 initially formed by the tissue-penetrating element 102.

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It is to be appreciated and understood that the showings of Figures 8a-8h and the following detailed description are impended to describe and illustrate representative examples of the types of passageway-modifying apparatus which may be utilized in accordance with the present invention, and are not intended to exhaustively list and describe each and every possible type of passageway-modifying apparatus useable in accordance with the present invention.

Figure 8a shows a first embodiment of a passageway modifying apparatus 500a comprising an elongate tubular member having an annular, sharpened distal cutting tip 502 formed on the distal end thereof, and a hollow lumen 504a extending longitudinally therethrough. This embodiment of the passageway modifying apparatus 500a may be advanced over a guide wire GW which has been passed through the initial passageway or tract created by the tissue-penetrating element 102, such that the annular distal cutting tip 502 will debulk or enlarge the initial tract or passageway formed by the tissue-penetrating element 102, so as to provide an extravascular passageway 10 of the desired size and configuration. It will be appreciated that, suction or vacuum may be applied to the proximal end of the lumen 504a of this embodiment of the passageway-modifying apparatus 500a to facilitate the coring of tissue by the distal cutting tip 502 such that tissue which is severed by the annular distal cutting tip 502 will be drawn in the proximal direction through the lumen 504a, and may be collected in an appropriate collection vessel for subsequent pathological examination.

Figure 8b shows another embodiment of a passageway modifying apparatus 500b which comprises a tapered dilator having a generally cylindrical proximal portion 506, and a gradually tapered distal portion 508. A hollow lumen 504b extends longitudinally through this embodiment of the passageway modifying apparatus 500b

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such that the passageway modifying apparatus 500b may be advanced over a guide wire GW which has been inserted through the initial passageway or tract created by the tissue-penetrating element 102. As this passageway  
5 modifying apparatus 500b is advanced through such initially formed passageway or tract, the tapered distal portion 508 will dilate the passageway or tract to the enlarged diameter of the proximal portion 506 of the apparatus 500b. An optional energy-emitting band 510 may  
10 be mounted about the proximal portion 506 of the apparatus 500b, so as to emit heat or other energy to further modify the surface of the passageway 10 as the apparatus 500b is advanced therethrough.

Figure 8c shows a third embodiment of a passageway  
15 modifying apparatus 500c which comprises an elongate tubular member having an annular, sharpened distal cutting tip 512 which is similar to the distal cutting tip 502 of the embodiment shown hereabove in Figure 8a, but which is further adapted to emit energy (e.g, heat,  
20 vibration, laser light, etc.). In this embodiment of the apparatus 500c, an energy transition wire or member 514 extends through the tubular proximal portion of the apparatus 500c and is connected to the annular distal cutting tip 512 so as to transmit electrical energy,  
25 ultrasonic vibration, or any other suitable form of energy to the distal tip 512, to facilitate advancement of the distal tip 512 to the desired blood vessel wall or other extravascular tissue. The hollow lumen 504 formed through the apparatus 500c permits that apparatus 500c to  
30 be advanced over a guide wire which has been positioned within the initially formed passageway or tract created by the tissue-penetrating member. Electrical current or other energy will be passed through the energy transmitting wire or member 514 during advancement of the  
35 apparatus 500c, such that heat or other energy is emitted by the distal tip to facilitate passage and advancement of the apparatus 500c through the tissue. It will be

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appreciated that a vacuum source (e.g., suction) may be attached to the proximal end of the lumen 504c to further facilitate advancement of the apparatus 500c through tissue, and to draw any cored tissue through the lumen 504c such that the removed tissue may be collected in collection vessel and submitted to subsequent pathological study.

Figure 8d shows a fourth embodiment of a passageway modifying apparatus 500d comprising an elongate tubular catheter 516 having a hollow lumen 504d extending longitudinally therethrough and an annular balloon 518 mounted on the outer surface thereof. A separate balloon inflation lumen (not shown) will extend through a proximal portion of the catheter 516 to permit inflation fluid to be injected into or withdrawn from the interior of the balloon 518. This embodiment of the passageway modifying apparatus 500d may be advanced over a guide wire GW which has been positioned within the initial passageway or tract created by the tissue-penetrating element, until the deflated balloon 518 is positioned within such initially created passageway or tract. Thereafter, the balloon 518 may be inflated to dilate or stretch the initially formed passageway or tract, to provide a modified extravascular passageway 10 having the desired diameter and/or configuration.

Figure 8e shows a fifth embodiment of a passageway-modifying apparatus 500e which comprises an elongate pliable catheter body made up of a proximal portion 520' and a distal portion 520'', positioned in longitudinal alignment with one another. The proximal and distal portions 520' and 520'' are connected to each other by two (2) elongate, bowable, cutting wires 522. A hollow lumen 504e extends through the proximal 520' and distal 520'' portions of the apparatus 500e, such that the apparatus 500e may be advanced over a guide wire GW which has been inserted through the passageway or tract initially created by the tissue or penetrating element

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102. A pull wire (not shown), or the guide wire itself may engage the distal portion 520'' of the catheter body such that the distal portion of the catheter body may be pulled in the proximal direction, thereby decreasing the gap between the proximal portion 520' and distal portion 520'' of the catheter body. This will cause the cutting wires 522 to bow outwardly, as shown by the phantom lines on Figure 8e. In operation, the apparatus 500e will be advanced over the guide wire GW and through the initially formed passageway or tract. Thereafter, the proximal portion 520'' of the catheter body will be drawn in the proximal direction to shorten the distance between the distal end of the proximal portion 520' and distal portion 520'' of the catheter body, thereby causing the cutting wires 522 to bow outwardly. Optionally, electrical current may be passed through the cutting wires such that the cutting action of the wires will be enhanced. Thereafter, the apparatus 500e will be withdrawn in the proximal direction through the initially formed passageway or tract created by the tissue-penetrating element 102, such that the outwardly bowed cutting wires 522 will enlarge the initially formed passageway or tract to thereby convert the passageway or tract into an enlarged slit-like extravascular passageway 10, in accordance with the present invention.

Figure 8f shows a sixth embodiment of a passageway-modifying apparatus 500f which comprises an elongate shaft member 530 having a pull-back cutting apparatus 532 mounted on the distal end thereof. The pull-back cutting apparatus 532 comprises a rigid member having a blunt distal surface 534 and an annular proximal cutting edge 536. A hollow lumen 504f extends longitudinally through the shaft 530 and pull-back cutting member 532 such that the apparatus 500f may be advanced over a guide wire GW which has been inserted in the initially formed passageway or tract created by the tissue-penetrating element 102. After the pull-back cutting member 532 has

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been fully advanced into the initially-formed passageway or tract, it will be retracted in the proximal direction such that the proximal cutting surface 536 will cut away tissue so as to enlarge or debulk the passageway.

5 Optionally, the cutting surface 536 may be rotated during the retraction of the pull-back member 532 to facilitate cutting of the tissue. Also, optionally, an anvil (not shown) may be positioned at the opposite end of the passageway 10 to provide counter-pressure against the  
10 cutting edge 536, thereby facilitating the cutting of tissue by the pull back cutting member 532. Tissue which is severed from the wall of the passageway by the proximal cutting surface 536 will be collected within the interior chamber 538 of the pull-back cutting member 532.

15 Figure 8g shows a seventh embodiment of a passageway-modifying apparatus 500g which comprises an elongate shaft 540 having a push-forward cutting member 542 mounted on the distal end thereof. A hollow lumen 504g extends longitudinally through the shaft 540 and  
20 cutting member 542 such that the apparatus 500g may be advanced over a guide wire GW which has been inserted through the initially-formed passageway or tract created by the tissue-penetrating element 102. The cutting member 542 comprises a distal portion 542' having a  
25 generally cylindrical outer surface and a proximal portion 542'' having an outwardly tapered outer surface. A sharpened annular cutting edge 544 is formed on the distal end of the distal portion 542' such that, as the apparatus 500g is advanced in the distal direction, the  
30 cutting edge 544 will cut a generally cylindrical mass of tissue, to thereby enlarge the initially-formed passageway or tract through which the apparatus 500g is advanced. Optionally, the sharpened annular cutting edge 544 of the apparatus 500g may be rotated during the  
35 advancement of the apparatus 500g. Also, an optionally anvil (not shown) may be positioned at the opposite end of the passageway 10 to provide counter-pressure against

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the cutting edge 544, thereby facilitating the cutting of tissue by the apparatus 500g.

Figure 8h shows an eighth embodiment of a passageway-modifying apparatus 500h. Comprising an elongate tubular member 550 having a lumen 504h extending longitudinally therethrough. A plurality of outflow apertures 554 are formed in the tubular member 550, within a region which is a spaced distance from the distal end of the tubular member 550. Also, a distal guide wire outlet aperture is formed in the distal end of the member 550 such that the apparatus 500h may be advanced over a guide wire GW which has been inserted through an initially formed passageway or tract created by the tissue-penetrating element 502. Proximal and distal sealing balloons 552', 552'' are formed about the outer surface of the tubular member 550, proximal and distal to the outflow apertures 554. As show in Figure 8h'', the tubular member 550 may be advanced over the guide wire GW until the outflow apertures 534 are located within the passageway 10 which is to be treated with a flowable liquid substance. Thereafter, the annular sealing balloons 552', 552'' will be inflated so as to seal off the opposite ends of the passageway 10. Thereafter, the desired flowable substance will be passed through the lumen 504h of the tubular member 550 such that it will flow out of the outflow apertures 554 and will fill the interior of the passageway 10, which remains sealed by the sealing balloons 552', 552''. After the flowable material has effected the desired treatment of the walls of the passageway 10, negative pressure may be applied to the lumen 504h to withdraw the flowable material from the interior of the passageway 10. Thereafter, the sealing balloons 522', 522'' will be deflated and the apparatus 500h will be withdrawn and removed from the passageway 10. Figure 8h' shows an alternative modification the device 500h' wherein no liquid outflow apertures 554 are formed on the tubular

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member 550, but rather, an energy transmitting member (not shown) such as a wire will extend through the body of the tubular member 550 and the region of the tubular member 550 between the sealing balloons 552', 552'' will be equipped with an electrode, electrocautery apparatus, resistance heater, laser, or other energy emitting apparatus such that the outer surface of the tubular member 550 between the sealing balloon 552', 552'' will become heated or will otherwise emit energy to treat the walls of the passageway 10 when the apparatus 500h'' becomes positioned within the passageway, in the manner described hereabove with reference to Figures 8h and 8h''.

iv. Apparatus for Longitudinal Compression and/or Support of Extravascular Passageways Formed Between Two Blood Vessels

In those applications where the extravascular passageways 10 of the present invention are formed between two (2) blood vessels (as in many of the above-described revascularization procedures) the presence of cavernous or loose tissue between walls of the blood vessels may be problematic, in that blood flowing through the passageway 10 may tend to infiltrate into such cavernous or loose tissues, thereby giving rise to blood leakage and/or hematoma formation.

One means for deterring such infiltration of blood into tissue or space between the adjacent blood vessel walls is the placement of a longitudinal passageway compression apparatus 22 within the passageway 10 so as to compress such cavernous or loose tissue, thereby preventing infiltration of blood thereinto. Furthermore, the deployment of such longitudinal compression apparatus 22 within the passageway 10 may additionally provide structural support within the passageway so as to maintain the patency of the passageway and prevent the passageway from unwanted flexing or closure due to movement of the adjacent tissues. It will be

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appreciated, however, that any such longitudinal compression apparatus 22 will preferably be constructed so as to provide sufficient longitudinal compression to prevent the unwanted infiltration of blood into the adjacent tissues but will not cause over-compression of such tissues as could cause iatrogenic ischemia and possible necrosis of such tissues. Figures 9a-9f''' and the following detailed description of such figures are directed to examples of specific longitudinal compression apparatus 22 which may be positioned within extravascular passageways 10 of the present invention to prevent tissue infiltration of blood and/or to provide structural support within the passageway. It is to be understood that Figures 9a-9f''' and the following detailed description are not intended to exhaustively list and describe all possible types of longitudinal compression apparatus 22 which may be useable in accordance with the present invention. Rather, these figures and the following detailed description are mere examples of the types of longitudinal compression apparatus 22 which are useable therefore.

The utility of the longitudinal compression apparatus 22 shown in Figures 9a-9f''' and described herebelow is not necessarily limited extravascular passageways 10 of the present invention, but may also be useable in connection with other methods for forming side-to-side connections (e.g., anastomoses) between juxtapositioned tubular anatomical passageways of the body such as blood vessels, fallopian tubes, etc.

Figures 9a-9a' show a first embodiment of a longitudinal compression apparatus 22a which comprises a first annular member 600 and a second annular member 602, which are directly alienable with one another and connectable to one another so as to longitudinally compress the blood vessel walls and other tissue which surround the passageway 10 formed between two blood vessels BV<sub>1</sub> and BV<sub>2</sub>. The first ring member 600 has a

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plurality of leg members 604 which extend from one side thereof. The second ring member 602 has a plurality of receiving apertures 606 which are positioned and configured to receive the leg members 604 therewithin.

5 Each leg members 604 has a bayonet connector 608 or other type of connector formed thereon such that, when the leg members 604 become inserted into the receiving apertures 606, the connector 608 will engage corresponding members or surfaces formed within the receiving apertures 606 so  
10 as to lock and hold the first and second ring members 600, 602 in a manner which causes longitudinal compression of the portions of the walls of blood vessels BV<sub>1</sub> and BV<sub>2</sub> and other intervening tissue which surrounds the passageway 10.

15 Figures 9b-9b''' show as second embodiment of a longitudinal compression apparatus 22b which comprises a resilient (e.g., superelastic) wire ring which has been bent into the configuration shown in Figure 9b having two upper arcuate segments 610', 610'' and two lower arcuate  
20 segments 612' and 612'', as shown. The apparatus 22b is initially mounted within the lumen 614 of a tubular catheter 616. An inner catheter member 618 having a reduced-diameter distal portion is coaxially positioned within the lumen 614 of the outer catheter 616, such that  
25 the longitudinally extended lower arcuate portions 612', 612'' of the apparatus 22b are captured and frictionally engaged between the outer surface of the distal reduced diameter portion of inner tubular catheter 618, and the inner luminal surface of the outer catheter 616, as shown  
30 in Figure 9b'. The outer catheter 616 is initially advanced through the passageway 10 wherein the apparatus 22b is to be deployed, and the inner catheter 616 is then advanced in the distal direction to push the longitudinally extended upper arcuate portions 610',  
35 610'' out of the distal end opening of the catheter 616, such that the upper arcuate portions 610', 610'' will resiliently bend outwardly so as to become positioned

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upon the luminal surface of the first blood vessel  $BV_1$ . Thereafter, the inner catheter 618 is drawn backwardly to release the longitudinally extended lower arcuate portions 612, 612', 612'' form frictional engagement and capture between the inner tubular catheter 618 and outer tubular catheter 616, and the outer tubular catheter 616 is withdrawn such that the lower arcuate portions 612', 612'' will pass out of the open distal end of the catheter 616 and will resiliently bend outwardly so as to abut against and engage the luminal surface of the second blood vessel  $BV_2$ , thereby compressing the walls of the blood vessels  $BV_1$  and  $BV_2$  and the cavernous or loose tissue positioned therebetween, in the manner illustrated in Figure 9b. The circular wire member of which the apparatus 22b is formed may be any suitable resilient type of material, and preferably may comprise a nickel-titanium alloy or polymer which exhibits superelasticity or high flexural properties within the range of temperatures which will be encountered by the apparatus 22b during deployment and implantation within the mammalian body.

Figure 9c shows a third embodiment of a longitudinal compression apparatus 22c comprising a first toroidal balloon 620 and a second toroidal balloon 622. The first and second toroidal balloons 620, 622 are positioned in longitudinal alignment with one another and are joined by a plurality of longitudinal connector members 624. The apparatus 22c is initially positioned within the passageway such that the deflated first toroidal balloon 620 is positioned adjacent the luminal surface of the first blood vessel  $BV_1$  and the deflated second toroidal balloon 622 is positioned adjacent the luminal surface of the second blood vessel 622, with the connector members 624 extending longitudinally through the passageway 10. Thereafter, the first and second toroidal balloons 620, 622 are inflated so as to longitudinally compress the portions of the walls of the blood vessels  $BV_1$  and  $BV_2$  and

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the tissue portions located therebetween, surrounding the passageway 10, as shown in Figure 9c. The toroidal balloon member 620, 622 may be inflated with a gelatinous or curable polymeric substance which will fully or partially solidify after the toroidal balloon member 620, 622 have become inflated, thereby avoiding any problem with down-line leakage or deflation of the toroidal balloon member 620, 622.

Figure 9d shows a fourth embodiment of a longitudinal compression apparatus 22d which comprises an annular first magnet 626 and an annular second magnet 628 connected by a plurality of longitudinal connector members 630. The apparatus 22d is initially deployed within the passageway 10 such that the first annular magnet 626 is positioned adjacent the luminal surface of the first blood vessel  $BV_1$  and the second annular magnet 628 is positioned adjacent the luminal surface of the second blood vessel  $BV_2$ . These annular magnets 626, 628 are then allowed to magnetically move toward one another such that the longitudinal connector members 630 will become engaged and will longitudinally connect the magnets, thereby compressing the adjacent portions of the walls of blood vessels  $BV_1$ ,  $BV_2$  and any tissue positioned therebetween, which surrounds the passageway 10.

Figure 9e shows a fifth embodiment of a longitudinal compression apparatus 22e comprising a first ring member 632 and a second ring member 634, which may be compressed inwardly and connected by inflation of first and second balloons 640, 642. At least one connector member 636 extends from the inner side of the first ring member 632. At least one corresponding receiving aperture (not shown) is/are formed in the second ring member 634, and such receiving aperture(s) is/are sized and configured to receive the connector member(s) 636, and to engage ratchet serrations or other engagable surfaces formed on the connector member(s) 636. The apparatus 22e is mounted within the passageway 10 by initially advancing the

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catheter 638, with the balloons 640, 642, deflated, through the passageway until the upper ring member 632 is in juxtaposition to and abutment with the luminal surface of the first blood vessel  $BV_1$ , and the second ring member 634 is in juxtaposition to and abutment with the luminal surface of the second blood vessel  $BV_2$ . Thereafter, the balloon 640, 642 are simultaneously inflated so as to urge the ring members 632, 634 inwardly toward one another. As the ring member 632, 634 are urged inwardly, the legs 636 of the first ring member 632 will advance further into the receiving apertures of the second ring member 634 and the ratchet serrations on leg 636 will be frictionally engaged and held within such receiving apertures (not shown). When the desired amount of compression of the walls of blood vessels  $BV_1$ ,  $BV_2$ , and tissue interposed therebetween and surrounding the passageway 10 has been achieved, the balloons 640, 642 may be deflated, and the catheter 638 bearing the deflated balloons 640, 642 will be withdrawn, leaving the apparatus 22e in place within the passageway 10.

Figures 9f-9f'''' show a sixth embodiment of a longitudinal compression apparatus 22f which may be mounted within the extravascular passageway 10 formed between two blood vessels  $BV_1$ ,  $BV_2$ , in accordance with the present invention. As shown, this apparatus 22f comprises a plurality of substantially parallel, elongate, pre-bent, resilient wire members 646 arranged in a generally cylindrical array. Optionally, a cylindrical connector member 648 formed of rigid or pliable material may be connected to each of the individual wire members 646 so as to hold them in the desired cylindrical array. Each wire member 646 is pre-bent so that, when unconstrained, the opposite ends of each wire member 646 will curl outwardly so as to cause the wire member to assume a generally "C" shaped configuration, as shown by the dotted lines in Figure 9f''. Initially, the apparatus 22f is mounted within the

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lumen 652 of a tubular delivery catheter 650. An inner tubular catheter member 654 is positioned coaxially within the lumen 652 of the delivery catheter 650. The inner catheter 654 has a distal portion 656 of reduced outer diameter. The apparatus 22f is mounted within the lumen 652 of the delivery catheter 656 such that the individual wire members 646 are constrained and held in substantially straight configurations. The proximal ends of the wire members 646 are captured between the outer surface of the distal portion 656 of the inner tubular catheter 654 and the inner luminal wall of the outer catheter 650 as shown in Figure 9f'. The apparatus 22f is implanted within the passageway 10 by initially passing the delivery catheter 650 into the passageway 10 such that the distal end of the delivery catheter is flush with the luminal surface of the first blood vessel BV<sub>1</sub> as shown in Figure 9f'. Thereafter, the inner tubular catheter 654 is advanced in the distal direction to cause the distal ends of the wire members 646 to emerge out of the distal end of the outer catheter 650, thereby allowing the distal end of the wire member 646 to curl outwardly and abut or become compressively inserted within the luminal surface of the first blood vessel BV<sub>1</sub>, as shown in Figure 9f''. Thereafter, the inner catheter 654 is retracted slightly in the proximal direction to release the proximal lens of the wire members 646 from frictional engagement and capture between the distal portion 656 of the inner tube 654 and the inner luminal surface of the outer tube 650. Thereafter, the entire catheter 650 is retracted in the proximal direction thereby liberating the entire apparatus 22f from the constraint of the surrounding catheter 650 and allowing the proximal ends of the wire members 646 to curl and to abut with or become compressively inserted into the luminal surface of the second blood vessel BV<sub>2</sub>, as shown in Figure 9f'''. In this manner, the apparatus, 22f serves to compress the walls of the blood vessels BV<sub>1</sub>,

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BV<sub>2</sub>, and any tissue interposed therebetween, in the area surrounding the passageway 10. Additionally, as shown in Figure 9f''', it will be appreciated that in embodiments wherein the cylindrical connector member 648 is employed, such cylindrical connector member may comprise a segment of synthetic or bioprosthetic graft material so as to form a substantially tubular inner lining within the passageway 10, as illustrated in Figure 9f''''.

It will be appreciated that, although the apparatus 22f has been described hereabove as a pre-bent resilient structure, the wire members 646 may alternatively be formed of malleable metal or other pressure-deformable material and a suitable deformation tool such as an inflatable balloon may be deployed within the introducer catheter 650 so as to volitionally pressure-deform the ends of the wire members 646 as they pass out of the catheter tube 650, thereby providing the desired pre-bent "C" shaped configuration.

v. A Preferred Passageway-Forming Catheter and System

Figures 10a-11d show two basic embodiments of a preferred passageway-forming catheter, and accompanying apparatus which combine to form a passageway-forming system, in accordance with the present invention. Figures 12a-13b provide step-by-step showings of the preferred method for utilizing the passageway-forming catheters and system shown in Figures 10a-11d, to create an extravascular passageway 10 between two adjacent blood vessels BV<sub>1</sub>, BV<sub>2</sub>.

With reference to Figure 10a-10c, there is shown a first embodiment of a preferred passageway-forming catheter device 100p, which comprises an elongate, flexible catheter body 700 having a lumen 702 extending longitudinally therethrough and terminating, at its distal end, in a distal outlet aperture 704. A tissue-penetrating element 102, which may comprise any suitable tissue-penetrating element including any of those shown

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in Figures 7a-7k and described hereabove, is disposed within the lumen 702 of the catheter body 700. It will be appreciated that the outlet aperture 704 and configuration of the lumen 702 may be modified to accommodate any of the suitable outlet schemes for passing the tissue-penetrating element out of the outlet aperture 704, including those penetrating-element outlet schemes shown specifically in Figures 6a-6i, and described hereabove.

10 The flexible catheter body 700 is preferably formed of a flexible polymer material such as nylon, Pebax, polyethylene, etc., or pliable metal tubing such as a thin walled hypotubing. A metal braid or other reinforcement material may be mounted upon or formed within the wall of the catheter body 700 to provide structural reinforcement and to permit the catheter body 700 to be rotated or torqued without undue disfigurement or crimping. Additionally, in embodiments wherein the tissue-penetrating element 102 comprises a pre-bent, resilient member or needle, a rigid tubular reinforcement member 701 may be positioned about a distal portion of the lumen 702 of the catheter body 700, as shown in Figure 10b, to provide rigid constraint for the pre-bent distal portion of the penetrating element 102 when the penetrating element 102 is retracted into the lumen 702 of the catheter body 700. The presence of such tubular reinforcement member 701 will additionally prevent any sharpened distal tip on the tissue-penetrating element 102 from scarring or penetrating into the relatively soft plastic material of which the catheter body 700 may be made.

A hand piece 706 is mounted on the proximal end of the pliable catheter body 700. The handpiece 706 comprises a rigid outer shell having a generally cylindrical, hollow inner cavity 712 formed therewithin. A proximal portion of the tissue-penetrating element 102 extends into the inner cavity 712 of the handpiece 706.

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An actuator button 710 is connected to the tissue-penetrating element 102, as shown in Figure 10c. The actuator button 710 may be depressed and advanced in the distal direction to cause the tissue-penetrating element 102 to pass out of the outlet aperture 704 for the purpose of forming an extravascular passageway 10 of the present invention. Thereafter, the actuator button 710 may be retracted in the proximal direction to retract the tissue-penetrating element into the lumen 702 of the flexible catheter body 700.

Optionally, an imaging catheter side car 720 may be attached to the distal portion of the flexible catheter body 700. This imaging catheter side car 720 comprises an elongate tube having a lumen 722 extending longitudinally therethrough. A window 724 is formed in the upper side wall of the side car 720, immediately adjacent the outlet aperture 704. An imaging catheter 50, such as an intravascular ultrasound catheter of the types commercially available from Boston Scientific/Cardiovascular Imaging, MA; Endosonics, Inc., Pleasonton, CA; and Hewlett-Packard, North Andover, MA., is insertable into the lumen 722 of the side car 720 such that the sensor portion 52 (e.g., portion where the imaging ultrasound is emitted and received) is positioned next to window 724. The material of which the side car 720 is made is preferably a material which will prevent transmission of the type of energy (e.g., ultrasound) which is utilized by the imaging catheter 50, but the window 724 is either an open aperture or is covered with a material which may be permeated by the energy utilized by the imaging catheter 50. In this manner, the sensor portion 52 of the imaging catheter 50 will receive an image only of the area which is in alignment with the window 724. Additionally, the window 724 is preferably of a rectangular configuration and is confined to the side wall of the side car 720 which is immediately adjacent the outlet aperture 704 of the flexible catheter

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body 700. In this manner, such specific sizing, configuration and positioning of the window 724 may permit the user to accomplish precise rotational orientation of the catheter apparatus 100p by simply rotating the apparatus 100p until the target tissue (e.g., other blood vessel) is clearly viewed by the imaging catheter 50 through the window 724, thereby indicating that the outlet aperture 704 is positioned correctly so that subsequent passage of the tissue-penetrating element 102 out of the outlet aperture 704 will cause the tissue-penetrating element 102 to advance through the wall of the blood vessel in which the catheter apparatus 100p is located, and into the target tissue (e.g., other blood vessel). Moreover, such positioning of the window 724 will permit the imaging catheter 50 to be utilized to observe the actual movement and penetration of the tissue-penetrating member 102, thereby ensuring that the extravascular passageway is formed at the desired location.

As an alternative to formation of a window 724 at a discrete location within the side car 720, the distal end of the side car 720 may be located adjacent the site at which the tissue penetrating member 102 passes out of the catheter body 700 and the sensor portion 52 of the imaging catheter 50 may simply extend out of and beyond the distal end of the side car 720 such that it may clearly image the deployment and movement of the tissue-penetrating element 102. In this alternative arrangement the field imaged by the imaging catheter 50 will no longer be limited or inhibited by the window 724 and the imaging catheter 50 may be capable of imaging in a full 360° radius about the distal end of the side car 720. Accordingly, any suitable types of marker apparatus or marking materials may be formed on the catheter apparatus 100p or tissue-penetrating element 102p to permit the imaging catheter 550 to be utilized for the desired function of determining the correct rotational

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orientation of the catheter device 100p prior to deployment or actuation of the tissue penetrating element 102.

Additionally, as described hereabove, a guide wire lumen 726 may extend longitudinally through the tissue-penetrating element 102 and may terminate distally in a guide wire outlet aperture 728 formed in the distal end of the tissue-penetrating element 102. In this manner, a guide wire GW may extend through the tissue-penetrating element 102 and may be advanced out of guide wire outlet aperture 728.

In embodiments wherein the tissue-penetrating element 102 is provided with a guide wire lumen 726 and guide wire outlet aperture 728 at its distal end, the presence of a guide wire GW within such lumen 726 may be utilized as a means for accurately determining when the distal end of the tissue-penetrating element 102 has penetrated into the lumen of a target blood vessel or other cavity or open area. To accomplish this, continual or intermittent distally-directed pressure will be applied to the guide wire GW as the tissue-penetrating element 102 is advanced through the wall of the blood vessel in which the catheter apparatus 100p is located and through any other extravascular tissue through which the passageway 10 is to pass. So long as the distal end of the tissue-penetrating element 102 is in abutment with tissue, the guide wire GW will be prevented from emerging and advancing out of the distal end guide wire outlet aperture 728 and, accordingly, the distally directed pressure applied to the guide wire GW will be met with resistance due to the presence of the tissue abutting against the guide wire outlet aperture 728. However, when the distal end of the tissue-penetrating element 102 enters into the lumen of the target blood vessel or other open space, the guide wire outlet aperture 728 will immediately become uncovered and the guide wire GW will be permitted to rapidly advance out of the guide wire

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outlet aperture 728 in response to the distally directed pressure being applied thereto. Such rapid advancement of the guide wire GW will signal to the operator that the distal tip of the tissue-penetrating element 102 has, in fact, entered the lumen of the target blood vessel or other open space. At that point, advancement of the tissue-penetrating element 102 may be volitionally stopped, so as to avoid any possibility that the tissue-penetrating element will perforate the contralateral wall of the target blood vessel or other tissue on the other side of open area within which the passageway 10 is to extend.

Figure 10c'-10c''' provide a schematic illustration of an apparatus which may be incorporated into the passageway-forming catheter 100p to exert continuous or intermittent distally directed pressure on the guide wire GW, as described hereabove, for determining when the distal end of the tissue-penetrating element 102 has passed into the lumen of the target blood vessel or other open space. With reference to Figures 10c'-10c''', the apparatus 800 comprises one or more springs 802 which are connected, by way of a connector member 804 to a portion of the guide wire GW which protrudes out of the proximal end of the catheter body 700. It will be appreciated that the apparatus 800 may be incorporated within the inner cavity 712 of the handpiece 706, or may be formed as a separate unit which is mountable upon the proximal end of the handpiece 706.

As shown in Figure 10c, prior to commencement of the procedure, the guide wire GW may freely extend out of the outlet aperture 728 in the distal end of the tissue-penetrating element 102, thereby allowing the spring members 802 of the apparatus 800 to assume a relaxed (e.g., shortened) configuration.

Figure 10c'' shows that, when the tissue-penetrating element 102 is being advanced through tissue, the distal end of the guide wire GW will be maintained flush with

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the outlet aperture 728, and the spring members 802 of the apparatus 800 will become stressed (e.g., elongated) due to the distally-directed pressure being applied by the distal tip of the guide wire GW against the adjacent  
5 tissue.

Figure 10c''' shows that, when the distal tip of the tissue penetrating element 102 has emerged into the lumen of a blood vessel or other open area, the guide wire GW will immediately advance out of the guide wire outlet  
10 aperture 728, thereby allowing the spring members 802 of the apparatus 800 to once again assume their relaxed (e.g., shortened) configuration. This abrupt advancement of the guide wire and relaxation of the spring members 802 will signal to the operator, that the tissue-  
15 penetrating element 102 has arrived within the lumen of the blood vessel or other open space, and that further advancement of the tissue-penetrating element 102 should be ceased.

As stated hereabove it shall be appreciated and  
20 understood that the pressure-exerting apparatus described and shown in Figures 10c'-10c''' is optional need not necessarily be included within the catheter device 100p. Moreover, it shall be understood and appreciated that continuous or intermittent urging of the guide wire GW in  
25 the distal direction may be accomplished manually (i.e., by hand) without the need for the use of any apparatus.

Figures 11a-11d show the manner in which the preferred passageway-forming catheter and system 100p may be modified to accommodate the specific type of tissue-  
30 penetrating element 102f shown in Figure 7f and described hereabove. This particular tissue penetrating element is made up of an inner puncturing member 322 and a longitudinally advanceable outer sheath 326.

Figures 11a-11d show a modified preferred catheter  
35 device 100p' which, like the above-described embodiment of the catheter device 100p, comprises a flexible catheter body 700 having a lumen 702 extending

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longitudinally therethrough, a handpiece 706 having an inner cavity 712 formed therewithin, and an imaging catheter side car 720 having a lumen 722 and window 724 formed therewithin, all of which are described in detail  
5 hereabove.

In this embodiment of the catheter device 100p', the handpiece 706 is modified to incorporate first and second actuator buttons 710a, 710b. The first actuator button 710a is connected to the pre-bent resilient inner member  
10 322 having the sharpened trocar tip 324 on the distal end thereof. The second actuator button 710b is connected to the tapered pliable sheath 326 which is longitudinally advanceable over the inner member 322, in the manner described in detail hereabove with reference to Figure  
15 7f. Thus, in this modified embodiment of the catheter device 100p', the inner member 322 and surrounding sheath 326 may be independently advanced and retracted utilizing actuator button 710a, 710b.

It will be appreciated that, when the inner member  
20 326 is devoid any guide wire lumen, it will be optional to apply continuous or intermittent distally directed pressure to the outer sheath 326 to accomplish the same lumen-penetration-signaling function described hereabove with reference to Figures 10c'-10c'''. Accordingly, the  
25 constant or intermittent pressure spring apparatus 800 may be attached to the sheath 326 in this embodiment of the catheter device 100p' so as to continuously urge the sheet 326 in the distal direction, in the same manner described in the guide wire GW in Figures 10c'-10c''', or  
30 such may be accomplished (if desired) by manual technique.

The catheter devices 100 and other devices and apparatus described herein may be combined in various ways to form unique systems for performing the methods of the present invention. The systems described herein  
35 should be understood to be combinations of one or more of the various itemized functional components described. The components of these systems may be utilized in

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mechanical or temporal relationship to one another to accomplish the novel methods described herein, and may be used in any one of the numerous combinations possible that sufficiently accomplish the stated objectives. Such systems may include a catheter body dimensioned to fit within a blood vessel and advanceable to a location which is in proximity to an extravascular target or neighboring vascular target. The catheter can further be combined in some way with one or more of the described active or passive orientation means to assist in the proper positioning of the catheter in the blood vessel with respect to the target. Further, the catheter may incorporate at least one of the tissue-penetrating elements such that a passageway may be formed from the blood vessel to the target. The system may also incorporate a guide wire dimensioned to be inserted into the passageway, and introducible through the catheter such that it may enter the passageway and provide a rail to the target. The system may also incorporate the placement of one or more of the devices that are positionable or insertable into the passageway over the guide wire, such as channel sizing and maintenance means or other devices for accomplishing a therapeutic or diagnostic end-point. Also, the systems may include one or more of the various blood vessel blocking means such that a blood vessel in operative association with an extravascular passageway of the present invention may be blocked or occluded to allow the re-routing of blood.

vi. Operation of the Preferred Embodiments of the Passageway-Forming Catheter and System

Figures 12a-12d provide a step-by-step showing of the preferred method of using the first embodiment of the tissue-penetrating catheter device and system 100p shown in Figures 10-10c'''. .

Figures 13a-13b provide a step-by-step showing of the preferred method of using the second embodiment of

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the preferred passageway-forming catheter device and system 100p'.

With reference to Figure 12a-12d, an imaging catheter 50 is inserted into the lumen 722 of the side car 720 such that the imaging sensor portion 52 of the catheter 50 is positioned adjacent window 724. In this manner, the combination of the imaging catheter 50 with the passageway-forming catheter device 100' forms a "system" in accordance with the present invention. With the tissue-penetrating element 102 retracted into the lumen 704 of the flexible catheter body 700 such that the distal tip of the tissue-penetrating element 102 is housed within tubular reinforcement member 701, the system comprising the catheter apparatus 100p and imaging catheter 50 is inserted into the vasculature of a mammalian patient and advanced until the distal end of the catheter body 700 and distal end of the side car 720 are positioned within a first blood vessel  $BV_1$  located adjacent a second blood vessel  $BV_2$  with the invention of forming a passageway 10 between the first blood vessel  $BV_1$  and second blood vessel  $BV_2$ .

The catheter device 100p is then rotated until the imaging field IF viewed by the imaging catheter 50 through the window 724 clearly views the second blood vessel  $BV_2$  into which the passageway 10 is to extend. This indicates that the catheter device 100t has been placed in the correct rotational orientation to allow the tissue-penetrating element 102 to form the passageway 10 at the desired location, such that it will extend into the second blood vessel  $BV_2$ . Thereafter, the actuator button 710 will be advanced until the distal tip of the tissue-penetrating element 102 begins to penetrate through the wall of the first blood vessel  $BV_1$ . Optionally, intermittent or continuous distally directed pressure may be applied to the guide wire GW by hand (i.e., manually) or by a pressure-exerting apparatus 800,

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as advancement of the tissue-penetrating element 102 continues.

With reference to Figure 12b, as soon as the distal tip of the tissue-penetrating element 102 emerges into the lumen of the second blood vessel  $BV_2$ , the guide wire GW will promptly advance in the distal direction, thereby signaling to the operator that the advancement of the tissue-penetrating member 702 should be ceased. At that point, the operator will discontinue further advancement of the actuator button 710.

Thereafter, the actuator button 710 will be retracted to its full proximal point so as to retract the tissue-penetrating element 102 into the lumen 702 of the catheter body 700, while allowing the guide wire GW to remain extended through the newly-formed passageway 10 and into the lumen of the second blood vessel  $BV_2$ .

As shown in Figure 12c, the passageway-forming catheter device 100p and accompanying imaging catheter 50 may then be extracted and removed from the body, leaving the guide wire GW positioned through the first blood vessel  $BV_1$ , through the passageway 10 and into the second blood vessel  $BV_2$ .

As shown in Figure 12d, a passageway modifying apparatus 500, such as any of the types of passageway modifying apparatus 500 shown in Figure 8a-8h, may then be advanced over the guide wire GB to modify (e.g., enlarge, debulk, treat, coat, etc.) the passageway 10.

It will be appreciated that, after the step shown in Figure 12v has been completed, the guide wire GW may be left in place through the passageway 10 to allow any desired stents, stented grafts, or passageway constraining apparatus 22 as shown in Figures 9a-9f to be deployed within the passageway 10.

Figures 13a-13e illustrate a step-by-step preferred method for utilizing the modified embodiment of the passageway-forming catheter device and system 100p shown in Figures 11a-11b.

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Initially, the desired imaging catheter 50 is inserted into the lumen 722 of the side car 720 such that the imaging catheter 50 and passageway-forming catheter device 100p' will, in combination, a passageway-forming "system".

The passageway-forming catheter 100p and accompanying imaging catheter 50 are then advanced into the vasculature to a point where the distal ends of the catheter body 700 and side car 720 are positioned within a first blood vessel  $BV_1$ , immediately adjacent a second blood vessel  $BV_2$ , between which a passageway 10 is to be formed. The imaging catheter 50 is then energized such that the sensor portion 52 of the imaging catheter will receive an image within the image field IF through window 724. The catheter device 100p' is then rotated until the second blood vessel  $BV_2$  into which the passageway 10 is to extend is clearly imaged by the imaging catheter 50 through window 724. This indicates that the correct rotational orientation and position of the catheter device 100p' has been attained. Additionally, the catheter device 100p' may be longitudinally moved until the desired flow characteristics are observed within the second blood vessel  $BV_2$  in the image field IF, thereby indicating that the catheter device 100p is in its correct longitudinal position. Additionally, the imaging catheter 50 may be utilized to determine the distance between the first blood vessel  $BV_1$  and second blood vessel  $BV_2$ , so as to define the distance which the tissue-penetrating element 102f should be deployed to form the desired passageway 10 from the first blood vessel  $BV_1$  to the second blood vessel  $BV_2$ .

As shown in Figure 13a, after the catheter 100p' has been longitudinally and rotationally orientated, the tissue-penetrating element 102f is deployed out of the catheter body 700, and begins to advance through the wall of the first blood vessel  $BV_1$ . The outer sheath 326 of the tissue penetrating element 102f will be in a slightly

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retracted position such that the trocar tip 324 extends out of the distal end of the sheath 326 to accomplish the desired penetration through tissue.

During the advancement of the tissue-penetrating element 102f as shown in Figure 13a, manual pressure or pressure exerted by apparatus 800 may be utilized to apply distally directed pressure to the sheath 326. In this manner, when the trocar tip 324 of the tissue-penetrating element 102f enters the lumen of the second blood vessel BV<sub>2</sub>, the sheath 326 will immediately advance forwardly into the lumen of the second blood vessel BV<sub>2</sub>, thereby signaling to the operator that the desired passageway 10 has been formed and that any further advancement of the tissue-penetrating element 102f should be ceased.

Figure 13b shows that, after the sheath 326 has advanced into the lumen of the second blood vessel BV<sub>2</sub>, the elongate trocar tipped member 322 may be extracted and removed, thereby leaving the sheath 326 as a conduit through the passageway 10.

As shown in Figure 13c, a guide wire GW may then be passed through the lumen of the sheath 326 and into the second blood vessel BV<sub>2</sub>.

Thereafter, as shown in Figure 13d, passageway-forming catheter device 100p' and accompanying imaging catheter 50 may be extracted and removed from the body, thereby leaving the guide wire GW in place, and extending through the lumen of the first blood vessel BV<sub>1</sub>, through the passageway 10 and into the second blood vessel BV<sub>2</sub>.

Thereafter, as shown in Figure 13e, any suitable type of passageway-modifying apparatus 500 may be advanced over the pre-positioned guide wire GW to effect the desired modification of the passageway 10.

It will be appreciated that the invention has been described hereabove with reference to certain specific embodiments and examples only. No effort has been made to exhaustively describe all possible embodiments of the

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invention, or to provide examples of each and every way in which the invention may be practiced. Indeed, those skilled in the art will recognize that various additions, deletions, modifications and alterations may be made to the above-described embodiments and examples without departing from the intended spirit and scope of the invention. Accordingly, it is intended that all such additions, deletions, modifications and alterations be included within the scope of the following claims.

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**WHAT IS CLAIMED IS:**

1. A method for revascularization, said method comprising the step of:

5 a) forming an extravascular passageway between a first location on a blood vessel and a second location on a blood vessel, such that blood having a  $pO_2$  of at least 50 will flow through said extravascular passageway.

10 2. The method of Claim 1 wherein said first location and said second location are on at least one blood vessel of the heart.

3. The method of Claim 1 wherein said first location and said second location are on the same blood vessel.

15 4. The method of Claim 1 wherein said first location and said second location are on different blood vessels.

5. The method of Claim 4 wherein said blood vessels are a artery and a vein.

20 6. The method of Claim 4 wherein said blood vessels are a vein and a vein.

7. The method of Claim 4 wherein said blood vessels are an artery and an artery.

25 8. The method of Claim 4 wherein a plurality of said extravascular passageways are formed between said blood vessels.

30 9. The method of Claim 1 wherein said extravascular passageway is formed for the purpose of bypassing an obstructed, injured or diseased segment of a blood vessel.

10. The method of Claim 1 wherein said first location is on an artery and said second location is on a vein, such that blood will flow from said artery, through said extravascular passageway, and into said vein.

35 11. The method of Claim 10 wherein blood which has entered the vein through said extravascular passageway is

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subsequently caused to flow through said vein so as to retroperfuse tissue through the venous vasculature.

12. The method of Claim 11 wherein said blood is caused to flow through the vein so as to retroperfuse tissue through venous vasculature by:

b) blocking said vein at a location adjacent said extravascular passageway to cause blood which flows into said vein through said extravascular passageway to subsequently flow through said vein in a direction which will cause said retroperfusion of tissue through the venous vasculature.

13. The method of Claim 1 wherein the extravascular passageway formed in step a is a primary extravascular passageway formed between a first blood vessel and a second blood vessel such that blood having a  $pO_2$  of at least 50 will flow from the first blood vessel, through said extravascular passageway, and into the second blood vessel.

14. The method of Claim 13 wherein said method further comprises the step of:

b) forming at least one secondary extravascular passageway between said second blood vessel and another blood vessel of the heart such that blood which has entered the second blood vessel through the first extravascular passageway will subsequently flow into another blood vessel through said secondary extravascular passageway.

15. The method of Claim 14 wherein said blood is caused to flow into the other blood vessel through the secondary extravascular passageway by:

c) blocking the second blood vessel at a location adjacent the second extravascular passageway to cause said blood to flow from said second blood vessel through said second extravascular passageway and back into said other blood vessel.

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16. The method of Claim 1 wherein at least one of said first and second locations are on a blood vessel which is part of a system of blood vessels wherein an obstructed, injured or diseased segment of a blood vessel is present. 17. The method of Claim 1 wherein step a of said method is carried out by:

5  
10 i) providing a passageway-forming catheter device comprising an elongate flexible catheter body having a tissue-penetrating element passable therefrom so as to penetrate through the wall of a blood vessel in which said catheter body is inserted;

15 ii) inserting said catheter body into the vasculature and positioning said catheter body such that the tissue-penetrating element is located adjacent the location at which said extravascular passageway is to be formed;

20 iii) passing said tissue-penetrating element from said catheter body so as to form said extravascular passageway in accordance with step a of said method.

18. The method of Claim 17 wherein step i further comprises:

25 providing an orientation means for locating said first and second locations and for orienting the catheter device such that the tissue-penetrating element of the catheter will pass from said first location to said second location, thereby forming  
30 said extravascular passageway between said first location on a blood vessel and said second location on a blood vessel.

19. The method of Claim 17 wherein the tissue-penetrating element of the device provided in step i  
35 further incorporates a lumen through which a guide wire may be passed upon creation of said extravascular

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passageway by said tissue-penetrating element, and wherein said method further comprises the step of:

5           passing a guide wire through said lumen and allowing said guide wire to remain extended through said extravascular passageway following extraction and removal of said catheter, to thereby provide for subsequent advancement of one or more other apparatus through said passageway, over said guide wire.

10           20. A method coronary revascularization in a mammalian heart having arteries and veins formed therein, said method comprising the steps of:

              providing a passageway-forming catheter adapted to form an extravascular passageway between two  
15           blood vessels;

              inserting said catheter into a peripheral blood vessel and advancing said catheter into a blood vessel of the heart;

              utilizing said catheter to form at least one  
20           primary extravascular passageway between the blood vessel of the heart in which said catheter is positioned and another blood vessel of the heart, such that blood will flow from one of the blood vessels, through the extravascular passageway, and  
25           into the other blood vessel.

              21. The method of Claim 20 wherein said at least one passageway is formed between an artery of the heart and a vein of the heart such that blood from the artery will flow through at least one of said extravascular  
30           passageway(s) into the vein of the heart.

              22. The method of Claim 21 wherein arterial blood which as flowed from the artery of the heart into the vein of the heart is subsequently caused to flow through the vein so as to retroperfuse cardiac tissues through  
35           the cardiac venous vasculature.

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23. The method of Claim 22 wherein said arterial blood is caused to flow through the vein so as to retroperfuse cardiac tissue through the cardiac venous vasculature by blocking flow through the vein in an opposite direction, at a location adjacent an  
5 extravascular passageway.

24. The method of Claim 21 wherein the method further comprises:

utilizing said catheter to form at least one  
10 secondary extravascular passageway from said vein of the heart to an artery of the heart such that arterial blood which has entered said vein of the heart will subsequently flow through said at least one secondary extravascular passageway and into an  
15 artery of the heart, so as to perfuse cardiac tissues through the cardiac arterial vasculature.

25. The method of Claim 20 wherein said method is carried out for the purpose of bypassing an obstructed, injured or disease-affected segment of an artery of the  
20 heart.

26. The method of Claim 25 wherein said revascularization is performed in the heart of a mammal having a Circumflex Artery, a Great Cardiac Vein, an Anterior Interventricular Vein and a Left Anterior  
25 Descending Artery for the purpose of bypassing an obstructed, injured or disease-affected segment of the Circumflex Artery, wherein said method further comprises:

i. forming a primary extravascular passageway between the Left Anterior Descending Artery and the  
30 Anterior Interventricular Vein;

ii. forming a secondary extravascular passageway between the Great Cardiac Vein and the Circumflex Artery at a location downstream of the obstructed, injured or disease-affected segment  
35 thereof; and,

iii. causing blood to flow from the Left Anterior Descending Artery through the primary

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extravascular passageway, through the Anterior Interventricular Vein into the Great Cardiac Vein, and through the secondary extravascular passageway into the Circumflex Artery, downstream of the obstructed, injured or disease-affected segment thereof.

27. The method of Claim 26 wherein step iii is accomplished by blocking the lumen of the Anterior Interventricular Vein at a location adjacent the primary extravascular passageway.

28. The method of Claim 27 wherein step iii is further accomplished by blocking the lumen of the Great Cardiac Vein at a location adjacent the secondary extravascular passageway.

29. The method of Claim 25 wherein said revascularization is performed in the heart of a mammal having a Circumflex Artery, a Great Cardiac Vein, an Anterior Interventricular Vein, and a Left Anterior Descending Artery for the purpose of bypassing an obstructed, injured or disease-affected segment of the Left Anterior Descending Artery, wherein said method further comprises:

i. forming a primary extravascular passageway between the Circumflex Artery and the Great Cardiac Vein;

ii. forming a secondary extravascular passageway between the Anterior Interventricular Vein and the Left Anterior Descending Artery at a location downstream of the obstructed, injured or diseased-affected segment thereof; and,

iii. causing blood to flow from the Circumflex Artery, through the primary extravascular passageway, through the Great Cardiac Vein into the Anterior Interventricular Vein, and through the secondary extravascular passageway into the Left Anterior Descending Artery downstream of the

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obstructed, injured or disease-affected segment thereof.

30. The method of Claim 29 wherein step iii is accomplished by blocking the lumen of the Great Cardiac Vein at a location adjacent the primary extravascular passageway.

31. The method of Claim 30 wherein step iii is further accomplished by blocking the lumen of the Anterior Interventricular Vein at a location adjacent the secondary extravascular passageway.

32. A method for performing a medical procedure at an intracorporeal target location within a mammalian body, said method comprising the steps of:

- a) positioning, within a blood vessel a catheter device which comprises:
  - i) a flexible catheter body having a proximal end and a distal end;
  - ii) a tissue-penetrating element passable out of a first location on said catheter body to form an extravascular passageway which extends from the blood vessel in which the catheter is positioned to an intracorporeal target location outside of said blood vessel;
- b) orienting the first location of the catheter body relative to the intracorporeal target location such that the tissue-penetrating element may pass out of the first location of the catheter body to form an extravascular passageway between said blood vessel and said intracorporeal target location;
- c) passing the tissue-penetrating element out of the catheter body to form said extravascular passageway between said blood vessel and said intracorporeal target location; and,
- d) passing at least one procedure-performing apparatus through said extravascular passageway and

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utilizing said procedure-performing apparatus to perform said medical procedure at said intracorporeal target location.

33. The method of Claim 32 wherein said medical  
5 procedure is the delivery of a flowable substance, and wherein said procedure-performing apparatus comprises a tubular cannula through which said flowable substance may be passed into said extravascular location.

34. The method of Claim 32 wherein said medical  
10 procedure is the implantation of an implantable drug delivery apparatus, and wherein said procedure-performing apparatus is an implantation device for passing said drug delivery apparatus through said extravascular passageway and for implanting said delivery apparatus at said  
15 extravascular location.

35. The method of Claim 32 wherein said medical procedure is the implantation of radioactive matter for radiotherapy, and wherein said procedure-performing apparatus is an implantation apparatus operative to pass  
20 said radioactive matter through said extravascular passageway and to implant said radioactive matter at said extravascular location.

36. The method of Claim 32 wherein said medical procedure is the implantation of a stimulator apparatus  
25 and wherein said procedure-performing apparatus comprises an implantation apparatus for passing said stimulator apparatus through said extravascular passageway and for implanting said stimulator apparatus at said extravascular location.

37. The method of Claim 32 wherein said medical procedure is the implantation of a sensor apparatus and wherein said procedure-performing apparatus comprises an implantation apparatus for passing said sensor apparatus  
30 through said extravascular passageway and for implanting said sensor apparatus at said extravascular location.

38. The method of Claim 32 wherein said medical procedure is the implantation of an electrode apparatus

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and wherein said procedure-performing apparatus comprises an implantation apparatus for passing said electrode apparatus through said extravascular passageway and for implanting said electrode apparatus at said extravascular  
5 location.

39. The method of Claim 32 wherein said medical procedure is the implantation of a transmitter apparatus and wherein said procedure-performing apparatus comprises an implantation apparatus for passing said transmitter  
10 apparatus through said extravascular passageway and for implanting said transmitter apparatus at said extravascular location.

40. The method of Claim 32 wherein said medical procedure is the implantation of a receiver apparatus and  
15 wherein said procedure-performing apparatus comprises an implantation apparatus for passing said receiver apparatus through said extravascular passageway and for implanting said receiver apparatus at said extravascular location.

41. The method of Claim 32 wherein said medical procedure is the implantation of a transponder apparatus and wherein said procedure-performing apparatus comprises an implantation apparatus for passing said transponder  
20 apparatus through said extravascular passageway and for implanting said transponder apparatus at said  
25 extravascular location.

42. The method of Claim 32 wherein said medical procedure is the implantation of a support member apparatus and wherein said procedure-performing apparatus  
30 comprises an implantation apparatus for passing said support member apparatus through said extravascular passageway and for implanting said support member apparatus at said extravascular location.

43. The method of Claim 32 wherein said support  
35 member is a stent which is initially deployed in a compact configuration as it is passed through the extravascular passageway, and which is subsequently

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deployed to an operative configuration to impart structural support to at least one anatomical structure located at said extravascular location.

5       44. The method of Claim 32 wherein said medical procedure is the implantation of a marker apparatus and wherein said procedure-performing apparatus comprises an implantation apparatus for passing said marker apparatus through said extravascular passageway and for implanting said marker apparatus at said extravascular location.

10       45. The method of Claim 44 wherein said marker is formed of radiographically visible material.

46. The method of Claim 32 wherein said medical procedure is tissue ablation, and wherein said procedure-performing apparatus is a tissue ablating apparatus.

15       47. The method of Claim 32 wherein said medical procedure is tissue destruction, and wherein said procedure-performing apparatus is a tissue destruction apparatus.

20       48. The method of Claim 32 wherein said medical procedure is tissue cutting, and wherein said procedure-performing apparatus is a tissue cutting apparatus.

25       49. The method of Claim 48 wherein the medical procedure is transection of a nerve, and wherein said procedure-performing apparatus is a nerve-transecting apparatus.

30       50. The method of Claim 32 wherein the medical procedure is the sampling of a biological fluid, and wherein said procedure-performing apparatus is a cannula through which a sample of biological fluid may be aspirated from said extravascular location.

35       51. The method of Claim 32 wherein the medical procedure is a sampling of solid matter, and wherein said procedure-performing apparatus is an apparatus for removing a sample of solid matter from said extravascular location.

52. The method of Claim 51 wherein said medical procedure is a tissue biopsy, and wherein said procedure-

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performing apparatus is a biopsy tool operative to sever and retrieve a segment of tissue from said extravascular location.

53. The method of Claim 32 wherein said method  
5 further comprises:

withdrawing said catheter from the vasculature following performance of said medical procedure.

54. The method of Claim 32 further comprising:  
positioning a tubular cannula within said  
10 extravascular passageway and causing said tubular  
cannula to remain indwelling within said  
extravascular passageway following extraction and  
removal of said catheter.

55. The method of Claim 54 wherein said indwelling  
15 tubular cannula extends from said extravascular location  
to an intracorporeal location, so as to drain fluid from  
said extravascular location to said second location.

56. The method of Claim 54 wherein said indwelling  
tubular cannula is accessible from any extracorporeal  
20 location to permit desired matter to be delivered through  
said cannula to said extravascular location.

57. The method of Claim 56 wherein said cannula  
extends through said extravascular passageway, and  
through the vasculature, and is coupled to a subcutaneous  
25 injection port which is accessible from an extracorporeal  
location, to allow flowable matter to be percutaneously  
injected into said injection port and delivered to said  
extravascular location through said indwelling cannula.

58. The method of Claim 53 wherein said method  
30 further comprises:

closing the opening in the blood vessel from  
which said extravascular passageway was formed,  
following completion of said medical procedure.

59. The method of Claim 58 wherein the closing of  
35 said opening in the blood vessel is carried out by the  
deployment of a blood vessel wall closing apparatus  
selected from the group of apparatus consisting of:

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an energy-emitting device;  
a cautery device;  
a suturing device;  
a stapling device;  
5 an endovascular graft;  
a stented endovascular graft;  
a balloon;  
a coil;  
strands of coagulation producing materials;  
10 microfibrillar collagen;  
collagen sponge;  
cellulose gel; and,  
combinations thereof.

60. A catheter device insertable into a blood  
15 vessel and useable to form an extravascular passageway  
which extends through the wall of the blood vessel in  
which the catheter device is inserted, to an  
intracorporeal target location, said catheter device  
comprising:

20 a flexible catheter body having a proximal end  
and distal end;

a tissue-penetrating element passable out of a  
first location on the catheter body to form said  
extravascular passageway; and,

25 orientation means for determining at least the  
rotational orientation of the catheter body to  
facilitate proper positioning of the first location  
on the catheter body such that subsequent passage of  
the tissue-penetrating element from the catheter  
30 body will form said extravascular passageway between  
said blood vessel and said intracorporeal target  
location.

61. The device of Claim 60 wherein said first  
location is an outlet aperture formed in the distal end  
35 of said catheter body and said tissue penetrating element  
is passable out of said outlet aperture, and wherein said  
tissue-penetrating element is adapted to bend in a first

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direction as it passes out of said outlet aperture formed in the distal end of said catheter body, to thereby penetrate the wall of the blood vessel in which the catheter has been inserted.

5        62. The device of Claim 60 wherein said first location is an outlet aperture formed in the side wall of the catheter body, and wherein said tissue-penetrating element, when passed out of said outlet aperture located in the side wall of said catheter body will penetrate  
10 through the wall of the blood vessel into which the catheter has been inserted.

63. The device of Claim 60 wherein said tissue-penetrating element comprises an elongate, pliable needle having a sharp distal tip and a pre-bent resilient spine  
15 member positioned therewithin, said spine member being operative to cause said pliable needle to bend in said first direction.

64. The device of Claim 60 wherein said tissue-penetrating element is an elongate member which  
20 comprises:

- i) a pliable proximal shaft having a distal end, and
- ii) a sharpened tip member formed of rigid material and mounted on the distal end of said  
25 pliable proximal shaft.

65. The device of Claim 60 wherein said tissue-penetrating element comprises a resilient, pre-bent member having a sharpened distal tip.

66. The device of Claim 65 wherein said needle is  
30 formed of a material which is superelastic when inserted within the mammalian body.

67. The device of Claim 66 wherein said super elastic material is a nickel-titanium alloy.

68. The device of Claim 66 wherein said pre-bent  
35 resilient member is a hollow needle having a hollow lumen extending longitudinally therethrough.

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69. The device of Claim 66 wherein said pre-bent resilient member is a solid needle.

70. The device of Claim 60 wherein said tissue-penetrating element comprises an elongate member having  
5 a trocar tip formed on the distal end thereof, in combination with a tubular sheath disposed around said needle member and longitudinally moveable relative to said needle member.

71. The device of Claim 60 wherein said tissue-  
10 penetrating element comprises an elongate member having an energy-emitting distal tip formed thereon, said energy-emitting distal tip being operative to emit energy which will facilitate penetration of said tissue-penetrating element through tissue.

72. The device of Claim 60 wherein the energy-  
15 emitting distal tip on said tissue-penetrating element is selected from the group of energy-emitting apparatus consisting of:

20 a resistance-heated tip;  
a monopolar electrocautery tip;  
a bipolar electrocautery tip;  
an ultrasound-emitting tip member; and,  
possible combinations thereof.

73. The device of Claim 60 wherein said tissue-  
25 penetrating element comprises an elongate member having a distal end with a rotating tissue-severing apparatus formed thereon.

74. The device of Claim 60 wherein said tissue-  
penetrating element is a flow of energy passable out of  
30 said outlet opening formed in said catheter body.

75. The device of Claim 60 wherein said flow of energy is selected from the group of energy types consisting of;

35 laser light;  
heat;  
ultrasound; and,  
possible combinations thereof.

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76. The device of Claim 60 wherein said tissue-penetrating element comprises an elongate member having a lumen extending longitudinally therethrough, said lumen being connectable to a source of negative pressure so as to draw tissue into said lumen through the distal end of said tissue-penetrating element.

77. The device of Claim 60 wherein said tissue-penetrating element comprises:

a pre-bent resilient, tubular sheath having an open distal end; and,

an elongate member having a sharpened distal tip, said elongate member being disposed within said tubular sheath and advanceable therethrough, such that the sharpened distal tip will emerge out of the open distal end of the sheath;

said elongate member being constructed of material which is sufficiently pliable to conform to the pre-bent configuration of the tubular sheath.

78. The device of Claim 60 further comprising:

a side car apparatus connected to at least a distal portion of the flexible catheter body, said side car apparatus being configured to received therewithin an imaging catheter such that the imaging catheter may be utilized to observe passage of the tissue-penetrating element out of the first location on the catheter body.

79. The device of Claim 78 wherein said side car is formed of a material which is at least partially impermeable to the energy utilized by the imaging device, and wherein said side car further comprises:

a window formed in said side car immediately adjacent said first location on the catheter body to permit said imaging device to observe the passage of said tissue-penetrating element out of said first location on the catheter body and through the wall of the blood vessel in which the catheter is positioned.

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80. The device of Claim 79 wherein said window is positioned in alignment with the direction in which said tissue-penetrating element will pass during creation of said extravascular passageway;

5           said window thereby comprising at least a portion of said orientation means, the orientation of the first location on said catheter body being thereby controllable by rotating the catheter device until an imaging apparatus positioned within the  
10           side car is able to view the target area into which the passageway is to be formed, thereby ensuring that the catheter device is in proper rotational orientation prior to advancement of the tissue-penetrating element out of the outlet aperture.

15           81. The device of Claim 60 wherein the catheter body is formed of a flexible plastic material, and wherein a rigid tubular reinforcement member is disposed about a portion of the lumen of said catheter body, adjacent the outlet aperture, to prevent the tissue-  
20           penetrating element from resting in contact with the pliable plastic material of the catheter body when the tissue-penetrating element is retracted into the catheter body.

          82. The device of Claim 60 further comprising:  
25           a handpiece mounted on the proximal end of said catheter body, said handpiece having an actuator button which is connected to said tissue-penetrating element, said actuator button being advanceable in a first direction to advance said tissue-penetrating  
30           element out of said outlet aperture, and retractable in a second direction to retract said tissue-penetrating element into the lumen of said catheter body.

          83. A system comprising the passageway-forming  
35           catheter device of Claim 60 further in combination with:  
          an imaging apparatus which is usable in conjunction with said orientation means to further

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facilitate the proper positioning of the first location on the catheter body.

84. The system of Claim 83 wherein said imaging apparatus is selected from the group of imaging apparatus  
5 consisting of:

ultrasonic imaging apparatus;  
Doppler imaging apparatus;  
radiographic imaging apparatus;  
magnetic resonance imaging apparatus;  
10 electromagnetic imaging apparatus; and,  
possible combinations thereof.

85. The system of Claim 84 wherein said apparatus is an imaging catheter.

86. The system of Claim 85 wherein the passageway-  
15 forming catheter device further comprises a side car apparatus connected to at least a distal portion of the flexible catheter body, said side car apparatus being configured to receive the imaging catheter therewithin, such that the imaging catheter may be utilized to observe  
20 the passage of the tissue-penetrating element from the first location on the catheter body; and,

said imaging catheter being positioned at least partially within said side car apparatus.

85. The system of Claim 84 wherein said side car  
25 apparatus is formed of a material which is at least partially and permeable to the energy utilized by the imaging catheter, and wherein said side car apparatus further comprises:

a window formed in said side car apparatus  
30 immediately adjacent said first location on the catheter body to permit said imaging catheter to observe the passage of the tissue-penetrating element out of the first location on the catheter body and through the wall of the blood vessel in  
35 which the catheter body is positioned; and,

said imaging catheter being located within said side car adjacent said window so as to limit the

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field observed by said imaging catheter to that which is observable through said window.

86. The system of Claim 85 wherein said passageway-forming catheter device is torqueable such that said catheter device may be volitionally rotated until the imaging catheter is able to view the target area through said window, thereby ensuring that the first location on the catheter body is in the correct rotational position prior to passage of the tissue-penetrating element out of the first location on said catheter body.

87. The system comprising the catheter device of Claim 58 wherein the tissue-penetrating element comprises an elongate member having guide wire lumen extending longitudinally therethrough such that a guide wire may be advanced through said lumen upon formation of said extravascular passageway by said tissue-penetrating element, said system comprising:

said catheter device of Claim 58 further in combination with an elongate flexible guide wire which is passable through said guide wire lumen of said tissue-penetrating element.

88. A longitudinal compression apparatus useable to longitudinally compress tissue surrounding openings formed in first and second tubular anatomical conduits having lumens, wherein said first and second tubular anatomical conduits are in side-to-side juxtaposition to one another such that said openings are in alignment with one another, said longitudinal compression apparatus comprising:

a first portion positionable in abutment with the luminal surface of the first tubular anatomical conduit surrounding the opening therein;

a second portion positionable in abutment with the luminal surface of the second tubular anatomical conduit surrounding the opening formed therein;

means for connecting said first and second portions to each other, so as to longitudinally

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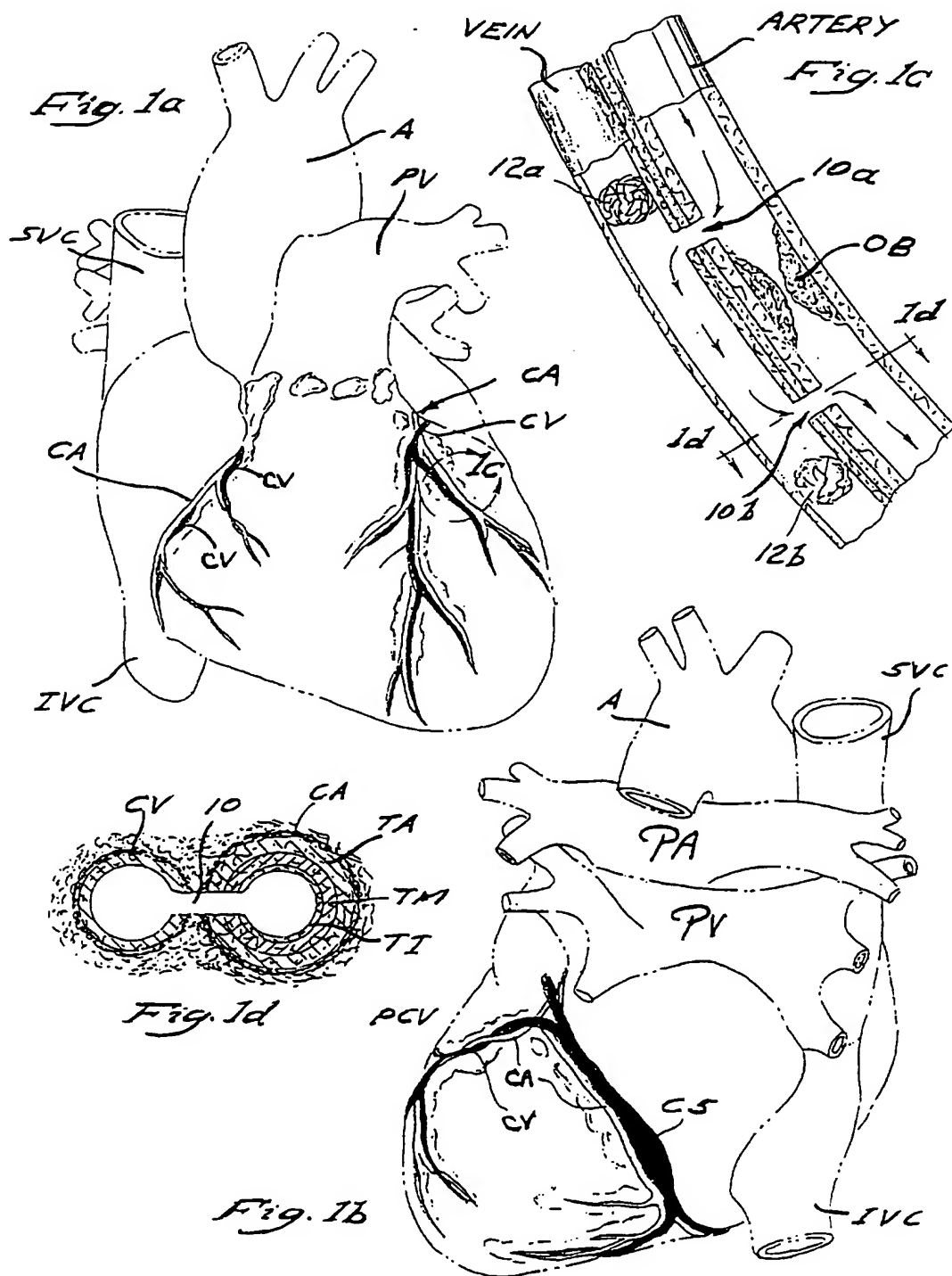
compress the tissue which surrounds the aligned openings of the first and second anatomical conduits and any extravascular tissue interposed therebetween.

5        89. The longitudinal compression apparatus of Claim 88 wherein said first and second portions comprise annular members positionable in abutment with said lumenal surfaces.

10       90. The longitudinal compression apparatus of Claim 88 wherein first and second portions comprise opposite ends of elongate wire members formed in a cylindrical array and extending through said first and second openings, said opposite ends of said wire members being outwardly bent so as to abut against and engage the  
15       lumenal surfaces of said first and second anatomical conduits.

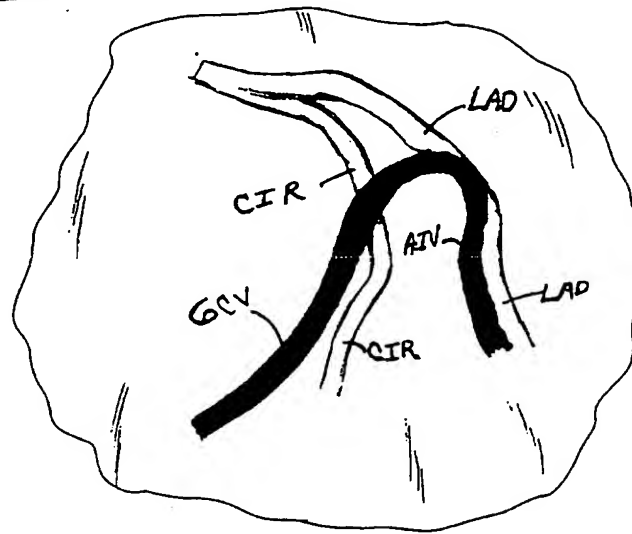
20       91. The longitudinal compression apparatus of Claim 90 wherein said wire members are pre-bent resilient wire members which, when positioned within said first and second openings and relieved of external constraint, will assume said bent configuration.

25       92. The longitudinal compression apparatus of Claim 90 wherein said wire members are plastically deformable, and wherein said device further comprises a pressure-exerting tool which is operative to bend the opposite ends of said wire members after said wire members have been positioned within said first and second openings.

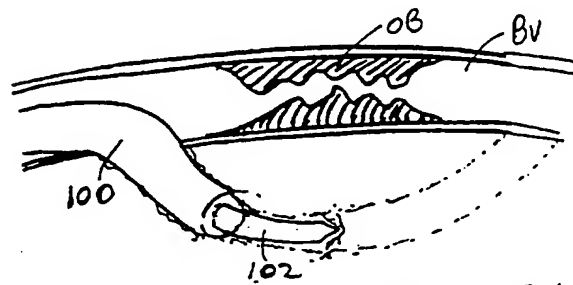


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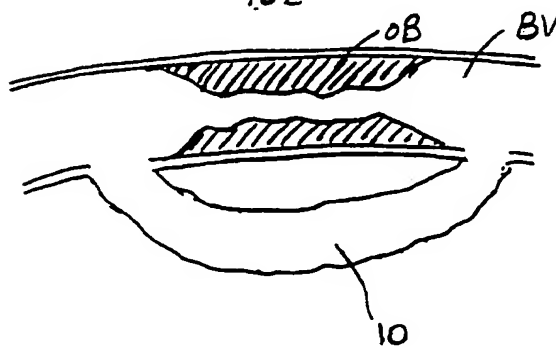
*Fig. 1e*



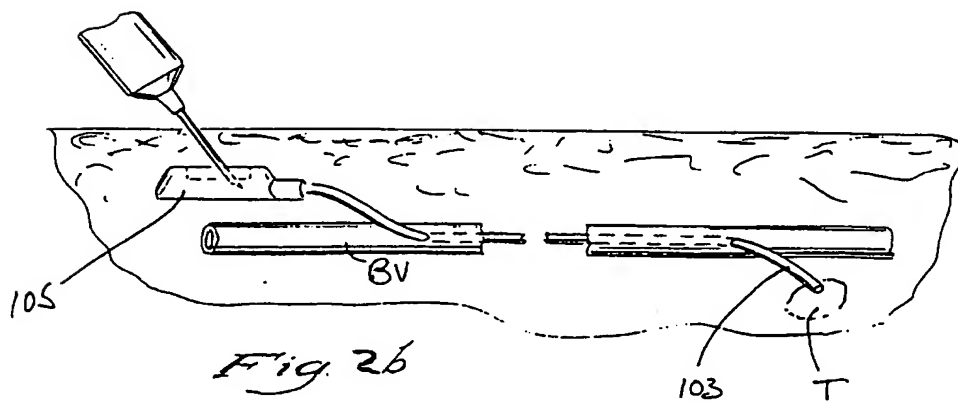
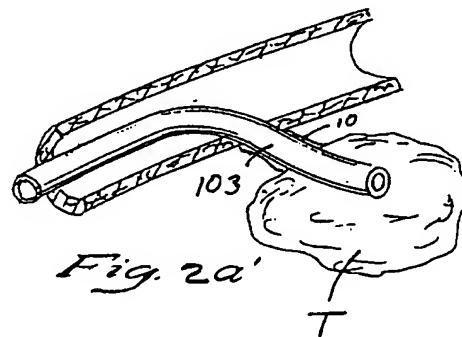
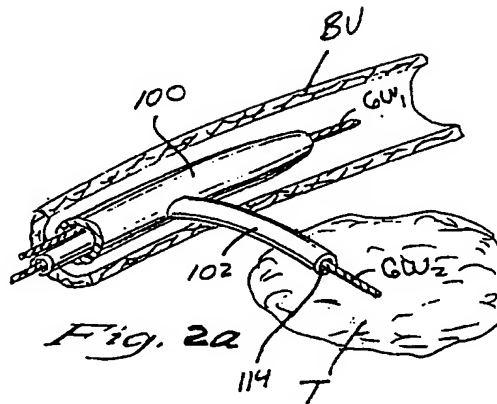
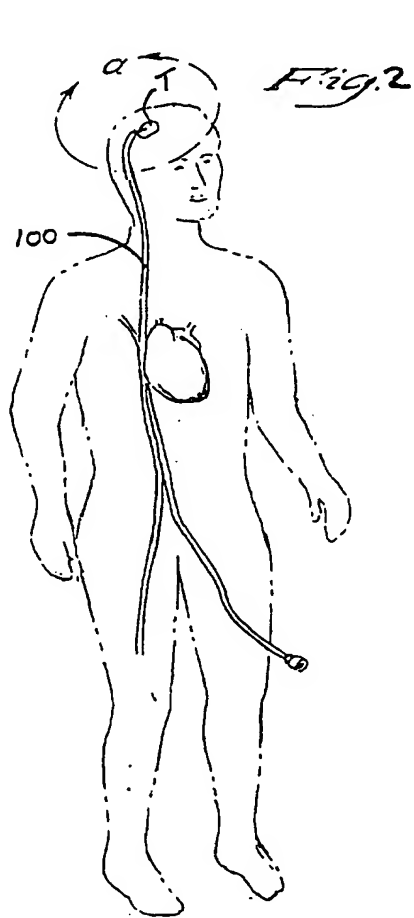
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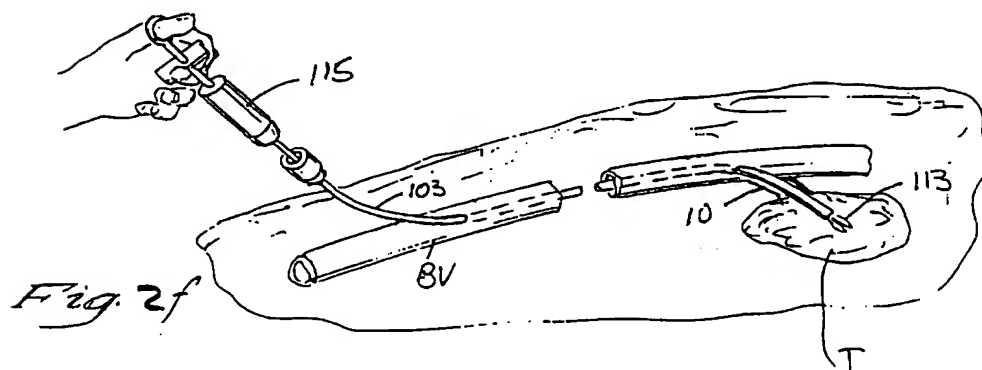
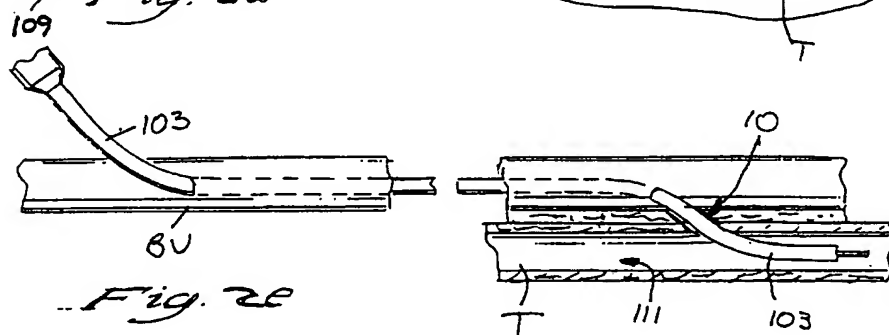
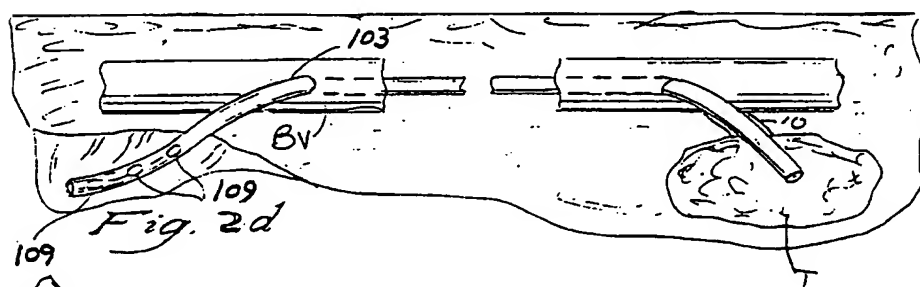
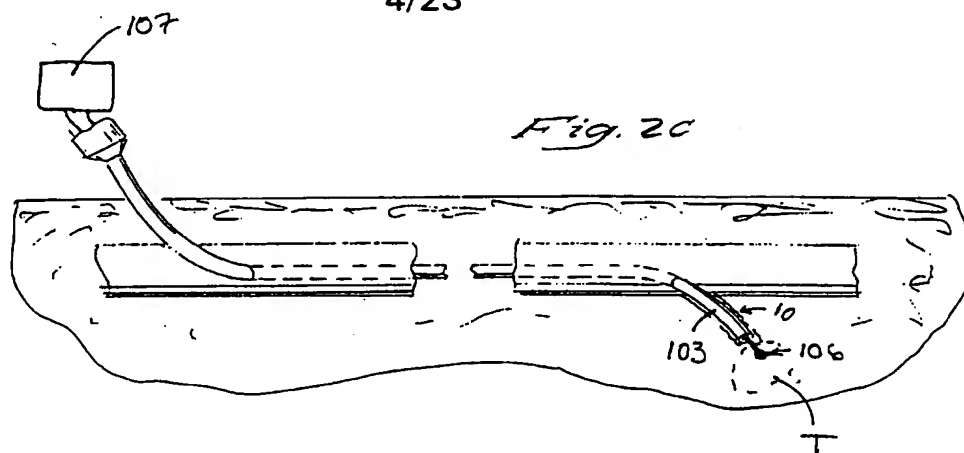
*Fig 1f'*



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Fig. 3a

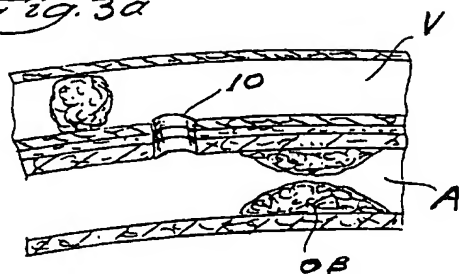


Fig. 3d

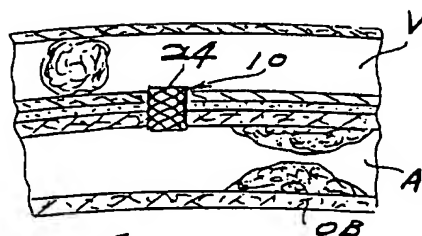


Fig. 3b

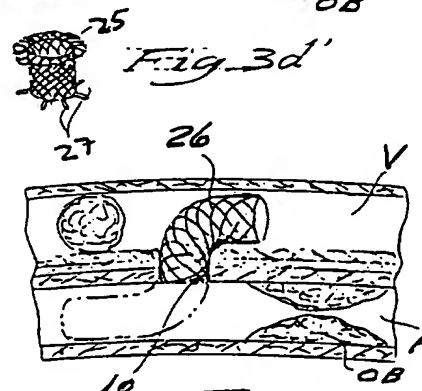
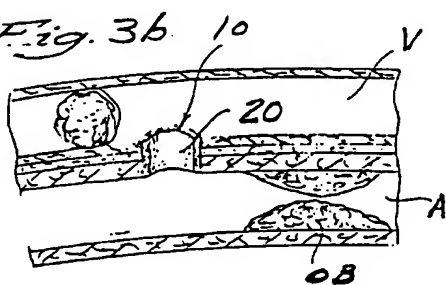
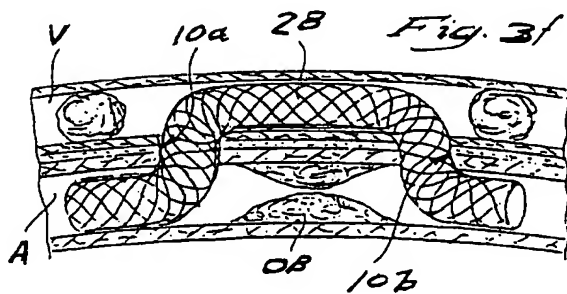
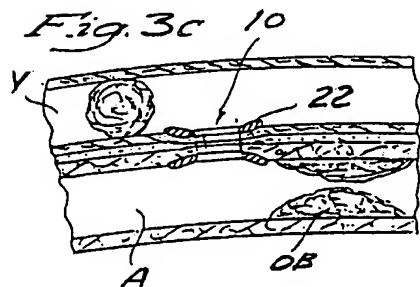
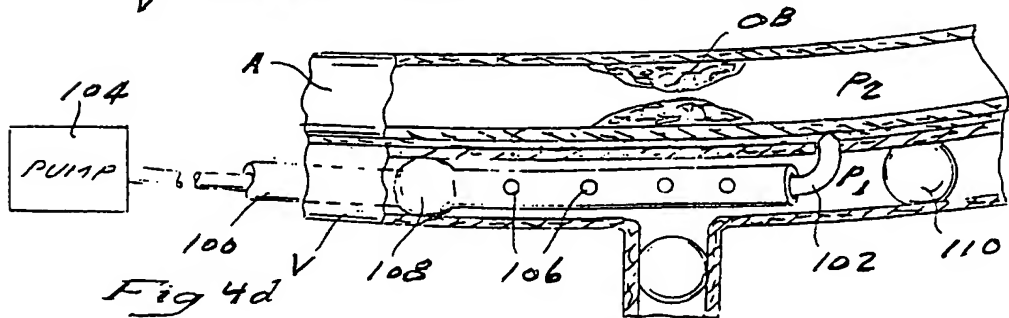
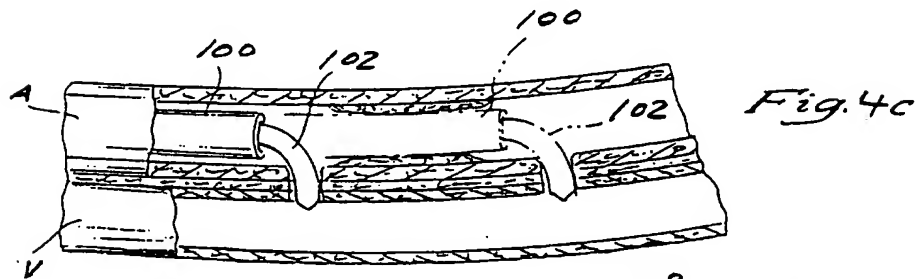
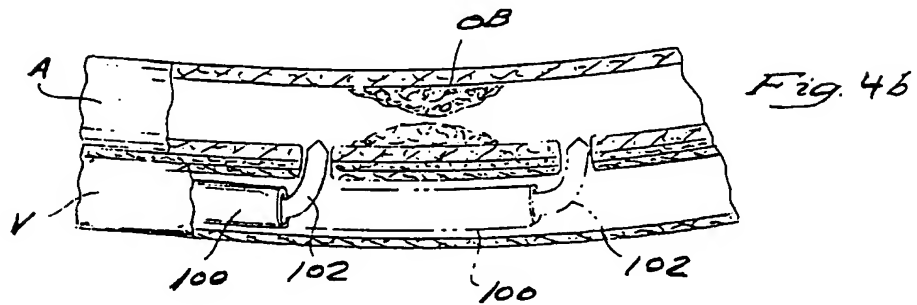
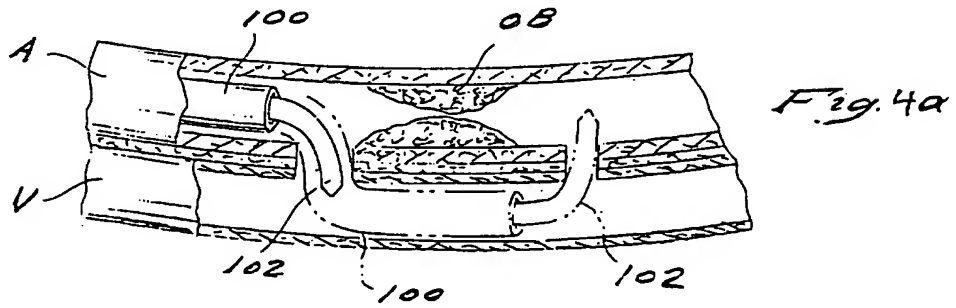


Fig. 3e

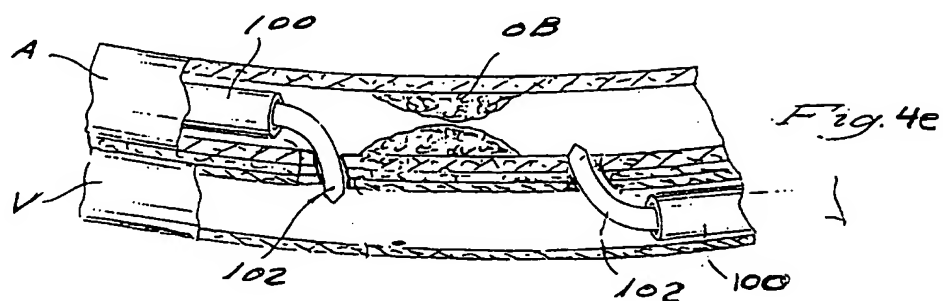
Fig. 3c



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Fig. 5a

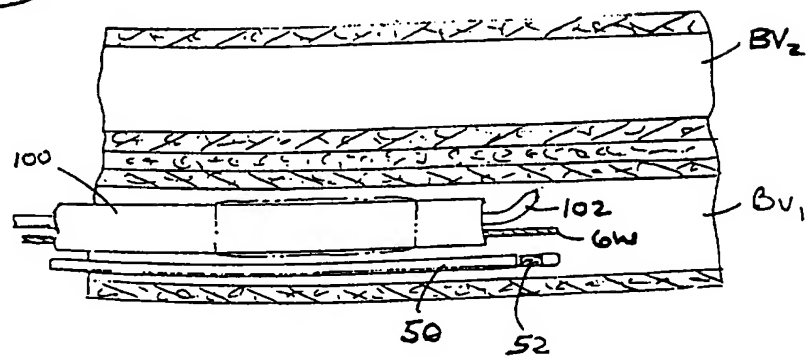


Fig. 5b

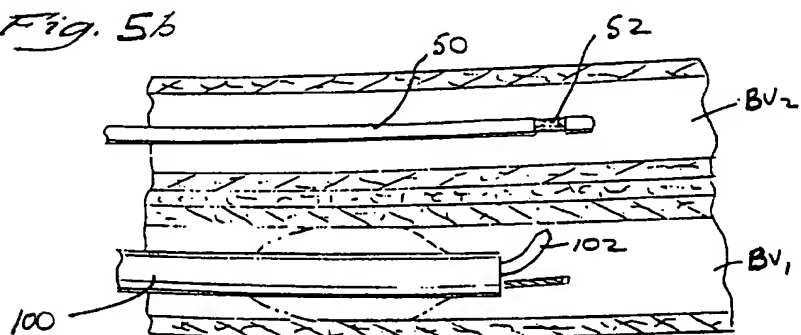


Fig. 5c

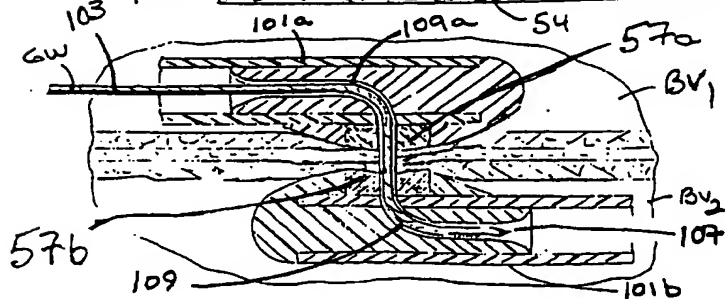
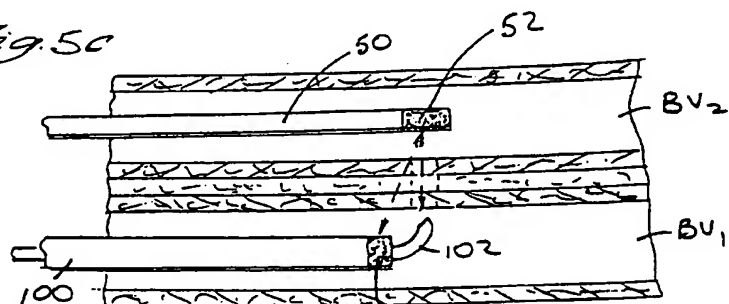
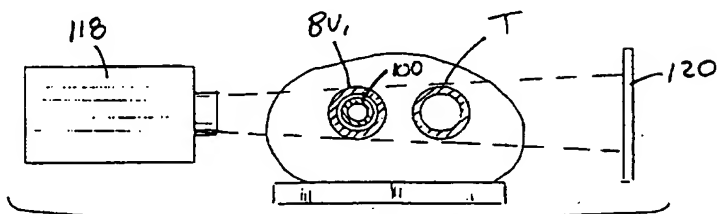
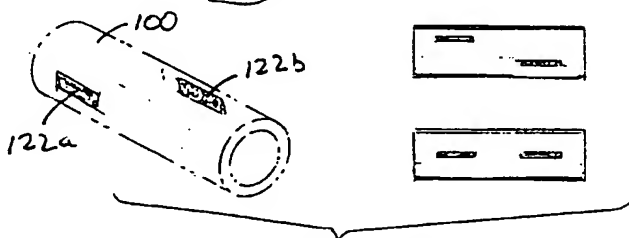


Fig. 5d

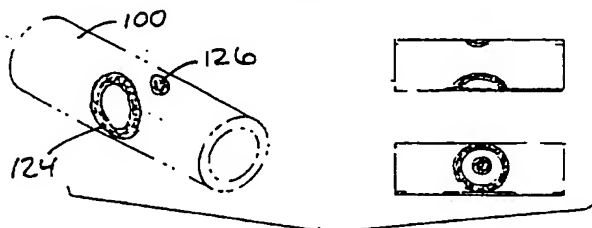
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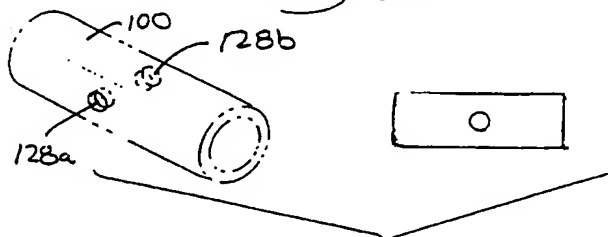
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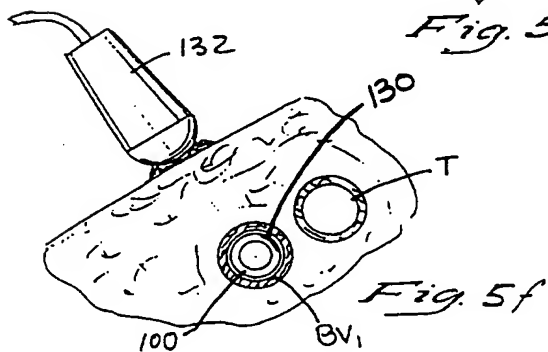
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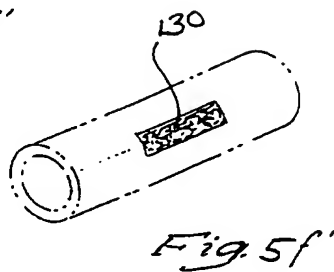
*Fig. 5e''*



*Fig. 5e'''*

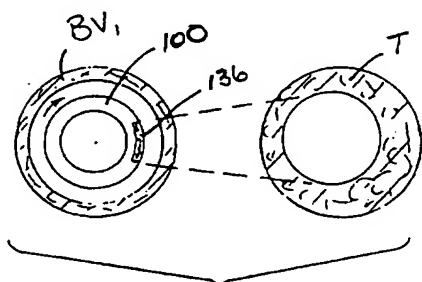
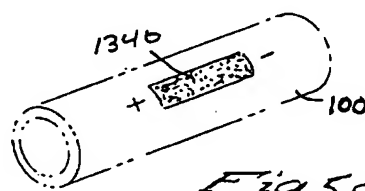
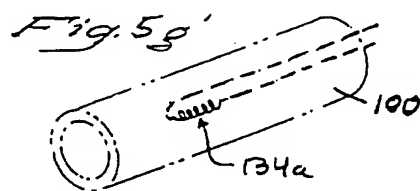
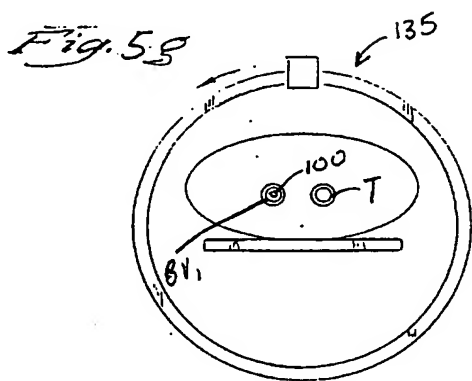
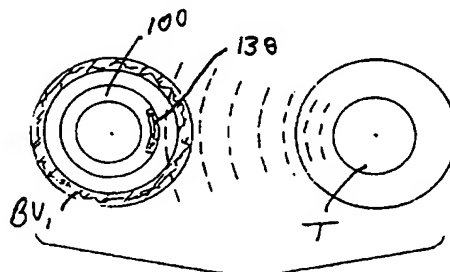
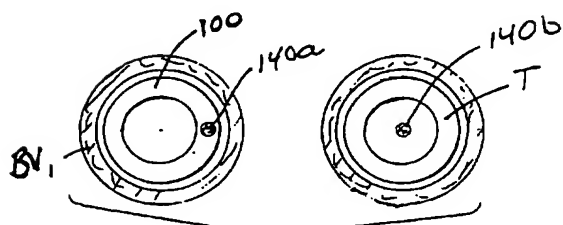
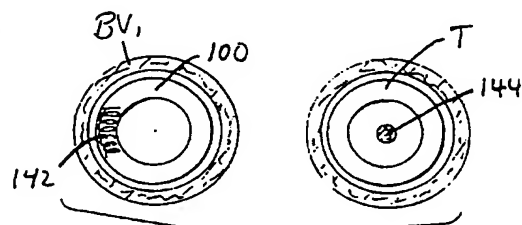
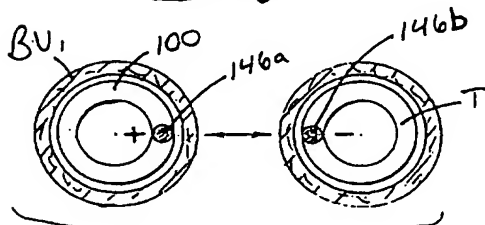


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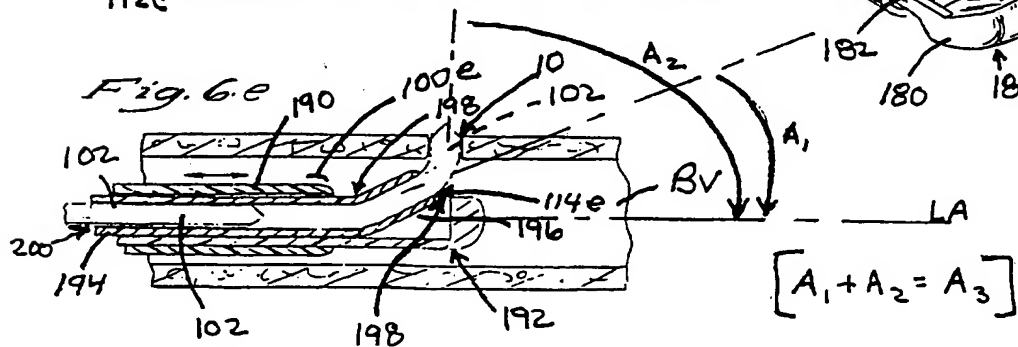
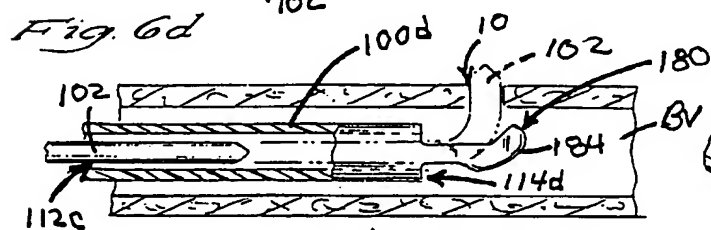
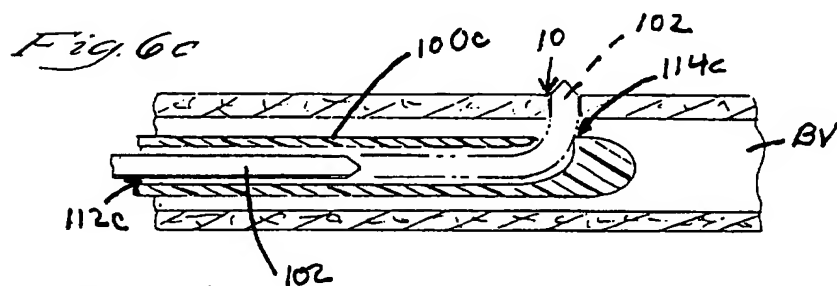
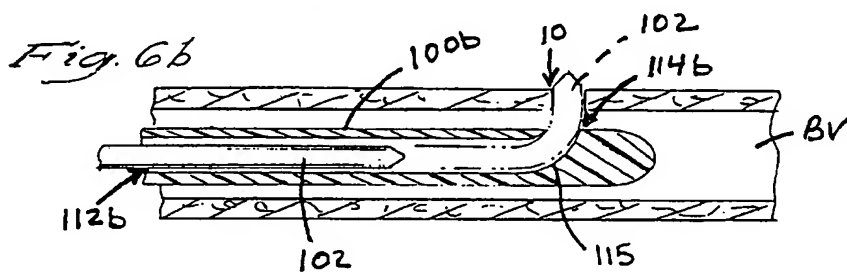
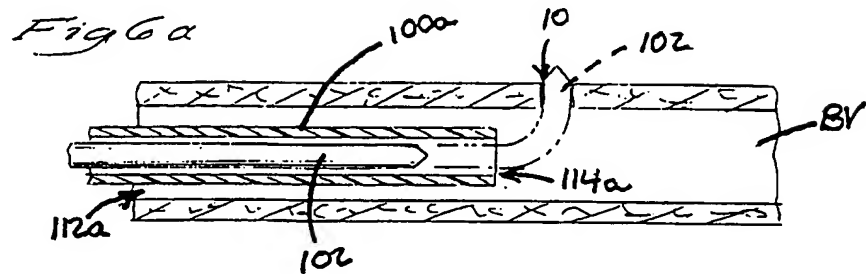


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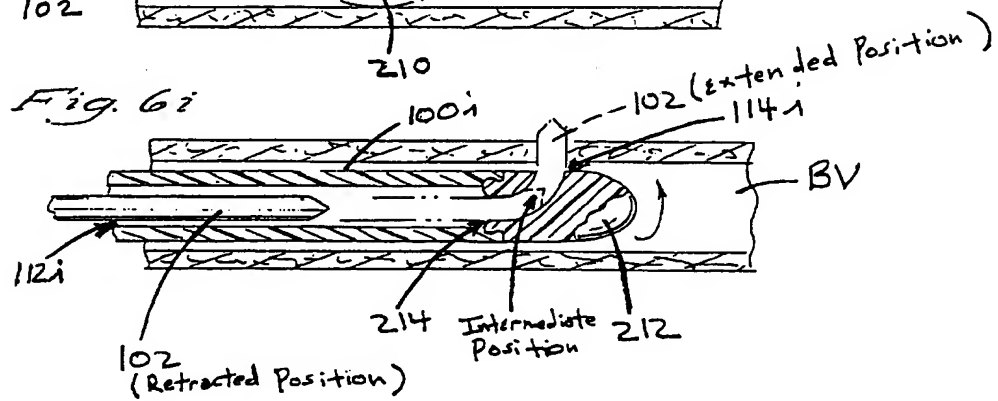
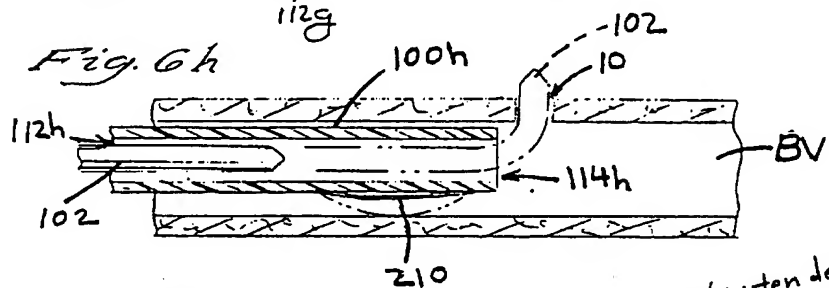
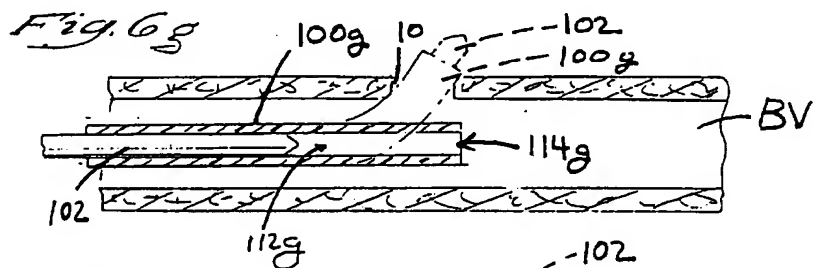
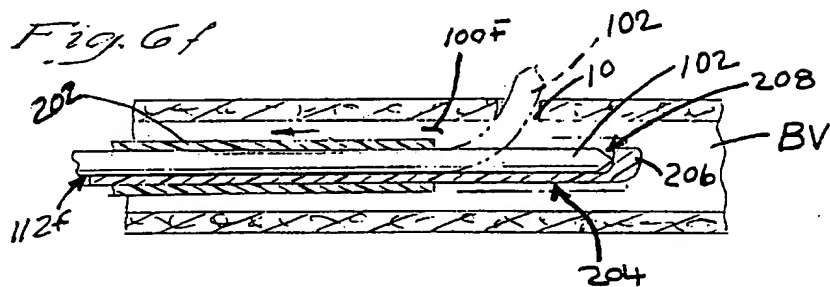
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*Fig. 5h**Fig. 5i**Fig. 5j**Fig. 5k**Fig. 5l*

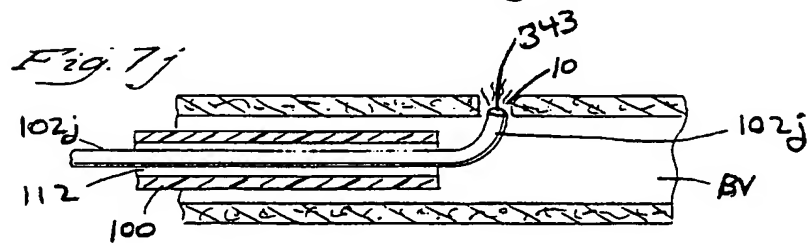
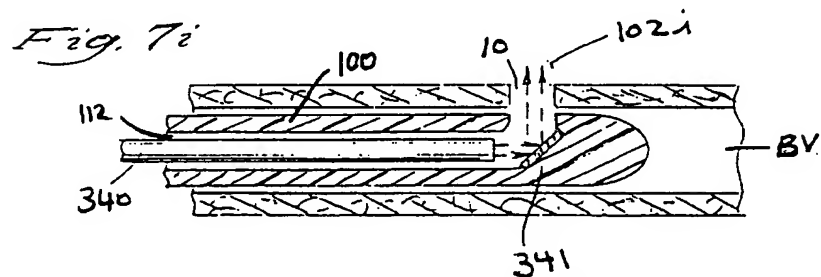
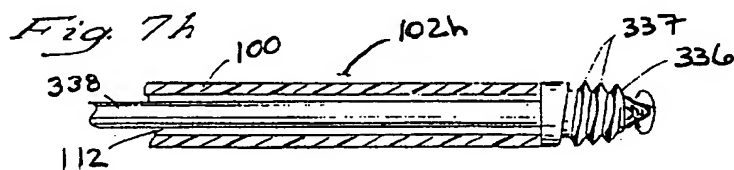
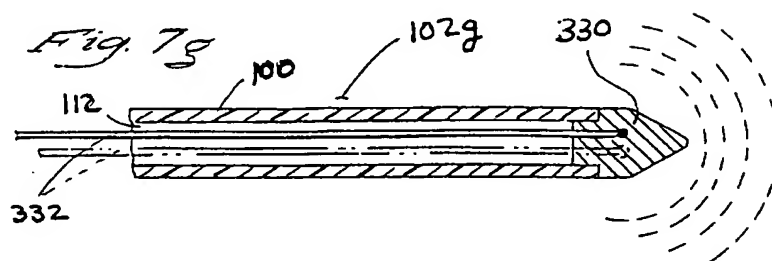
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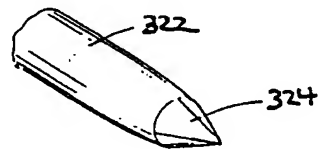
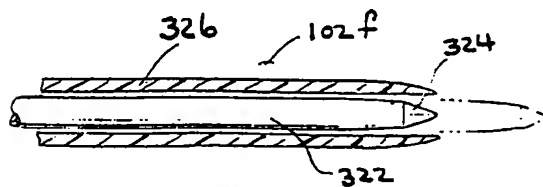
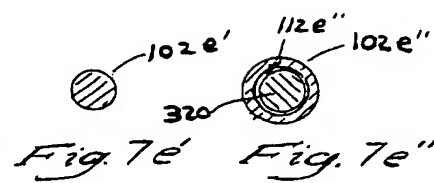
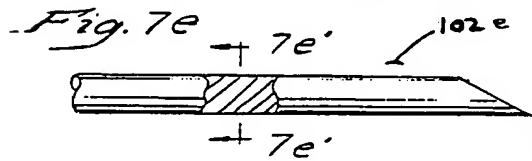
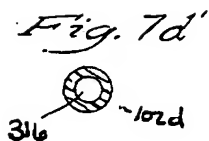
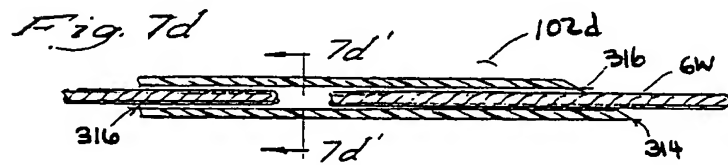
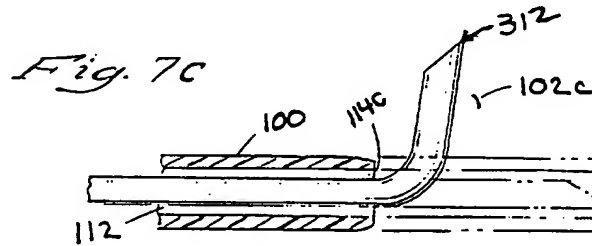
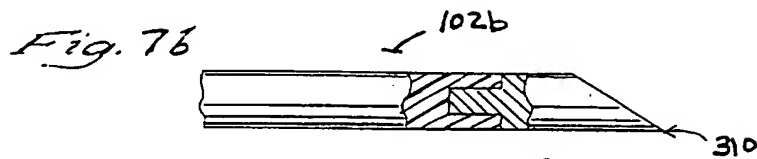
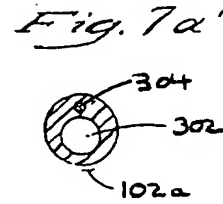
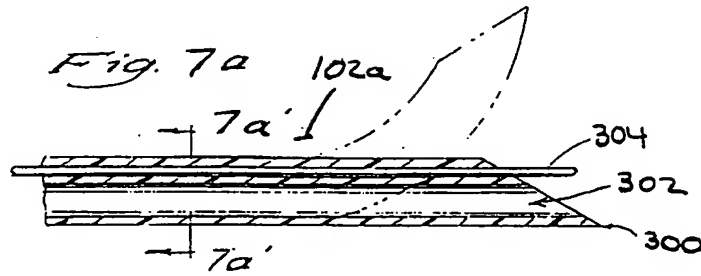
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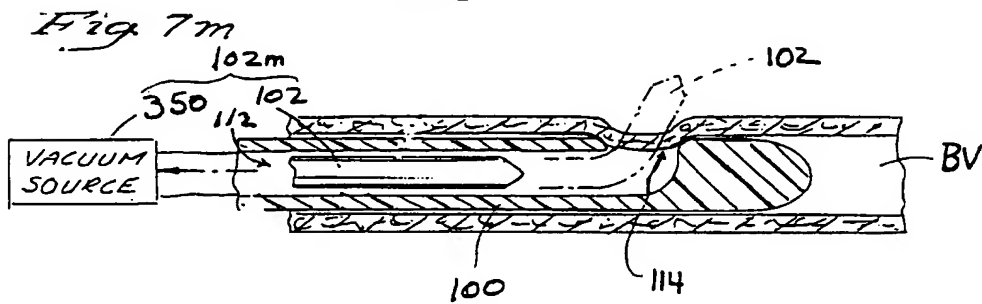
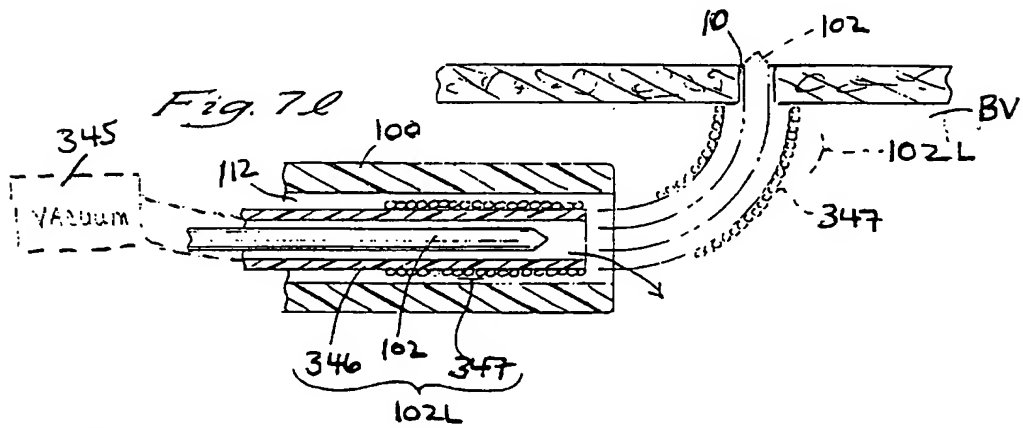
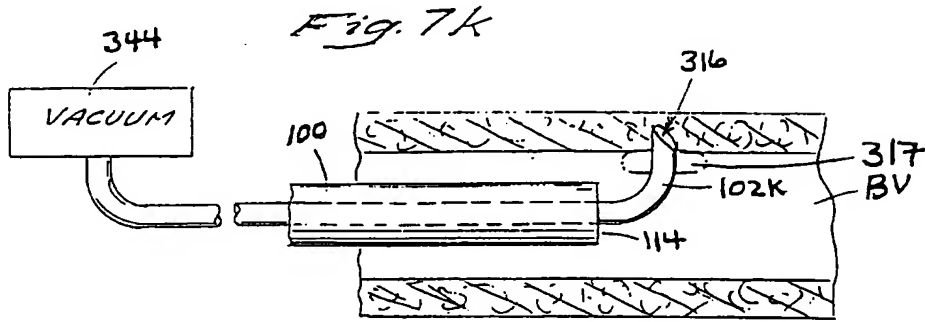
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Fig. 8a

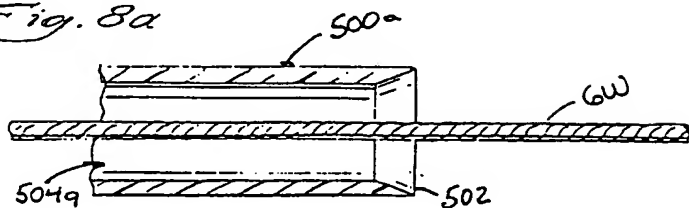


Fig. 8b

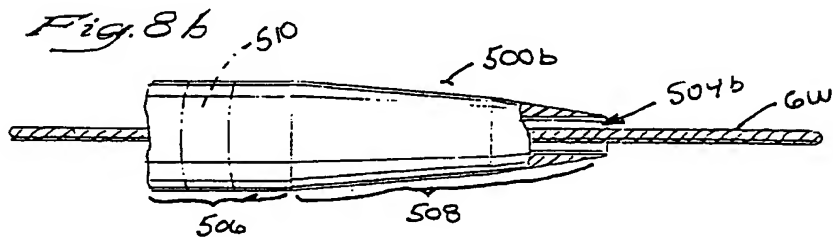


Fig. 8c

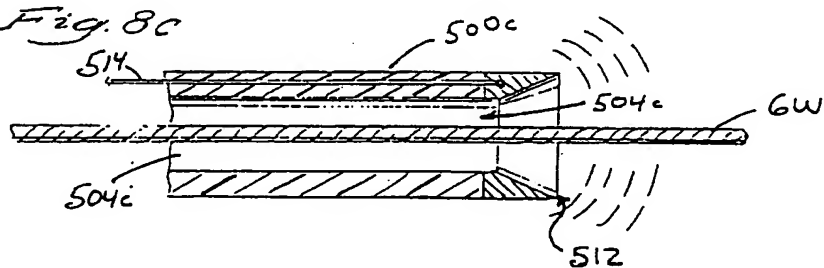


Fig. 8d

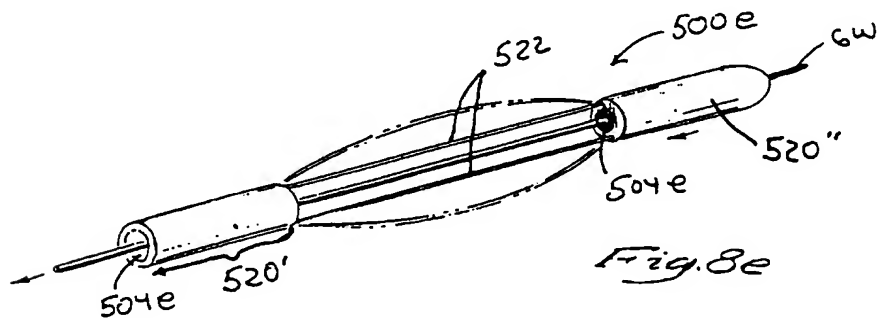
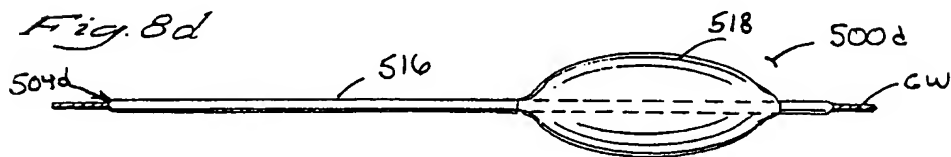


Fig. 8e

Fig. 8f

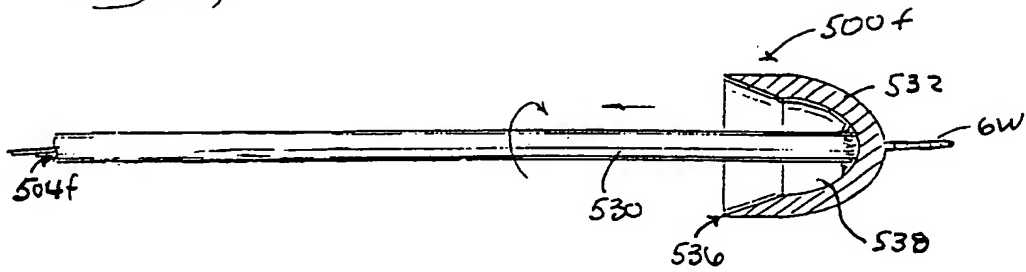


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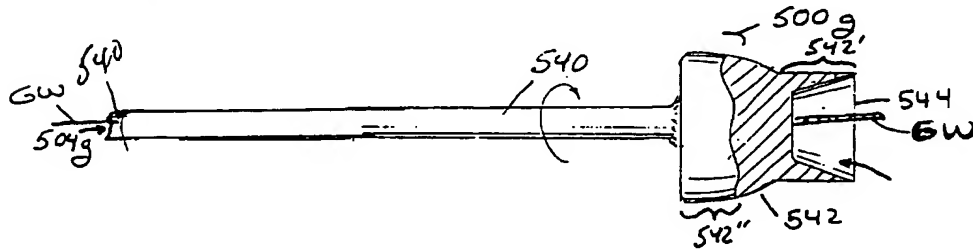


Fig. 8h

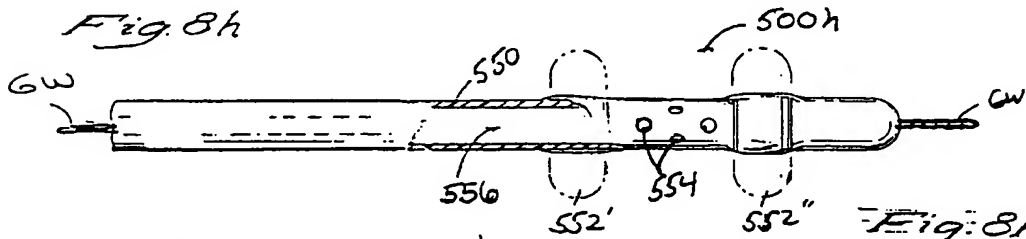


Fig. 8h''

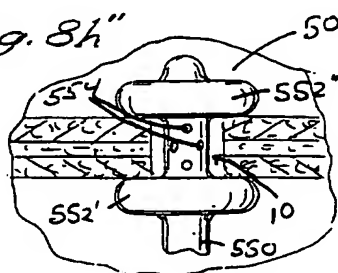
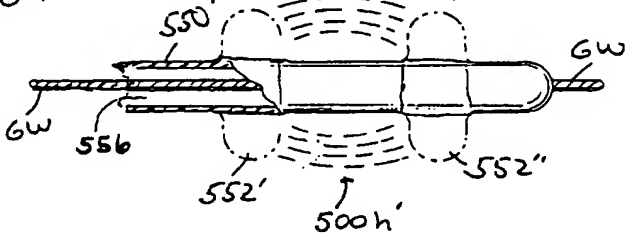
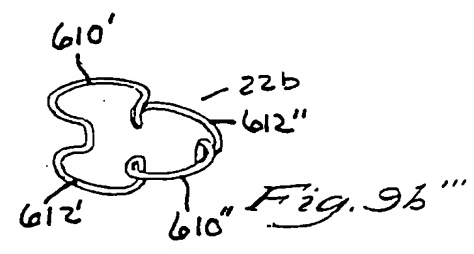
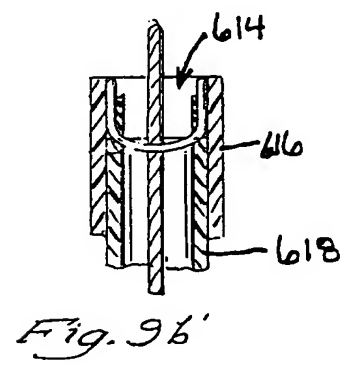
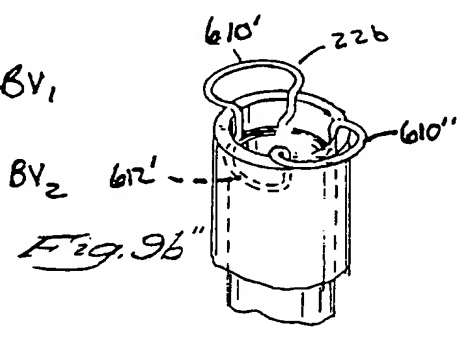
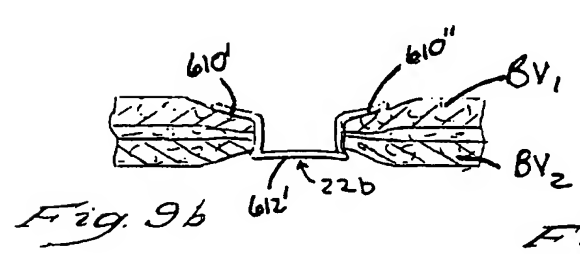
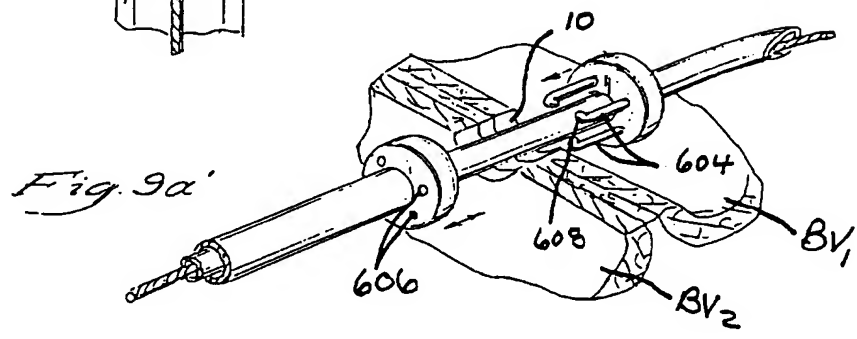
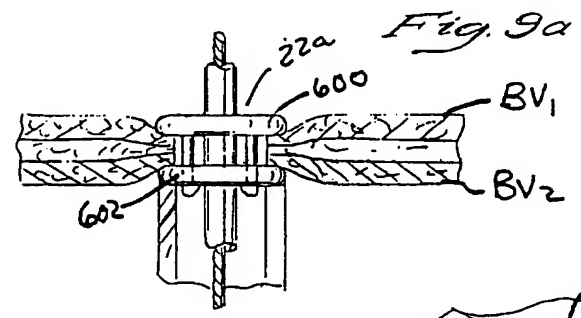


Fig. 8h'





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Fig. 13a

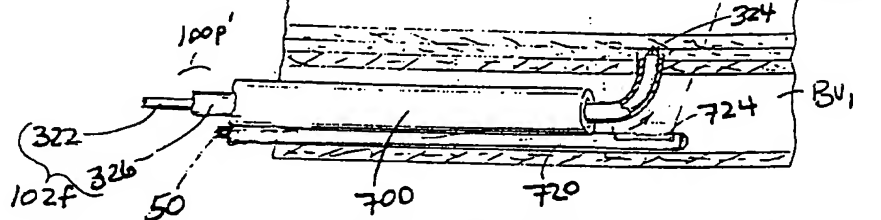


Fig. 13b

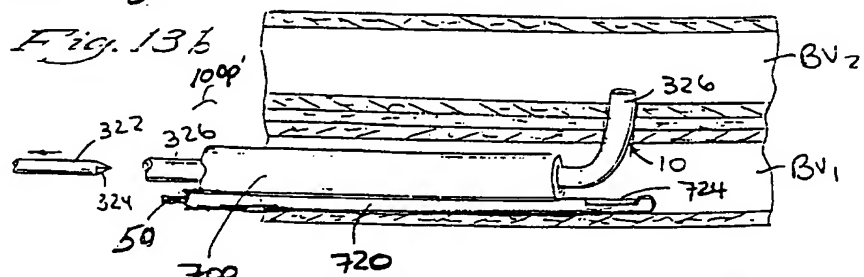


Fig. 13c

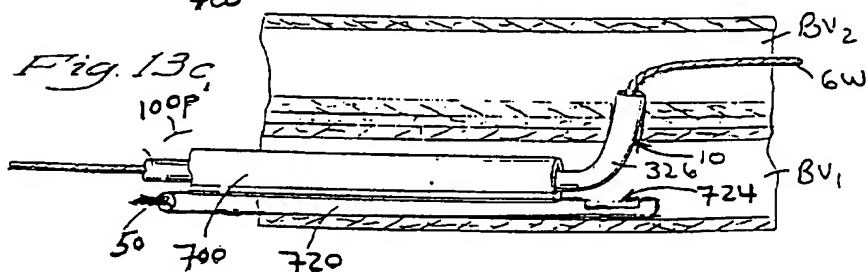


Fig. 13d

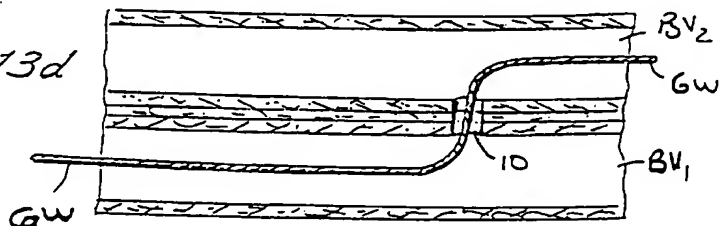
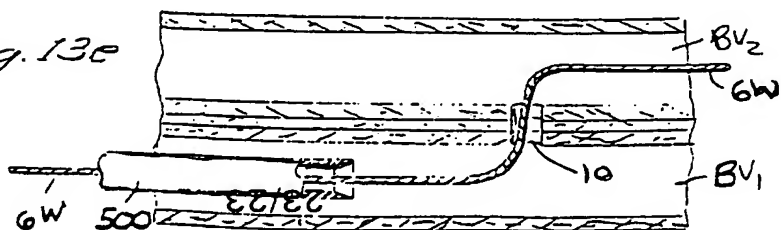
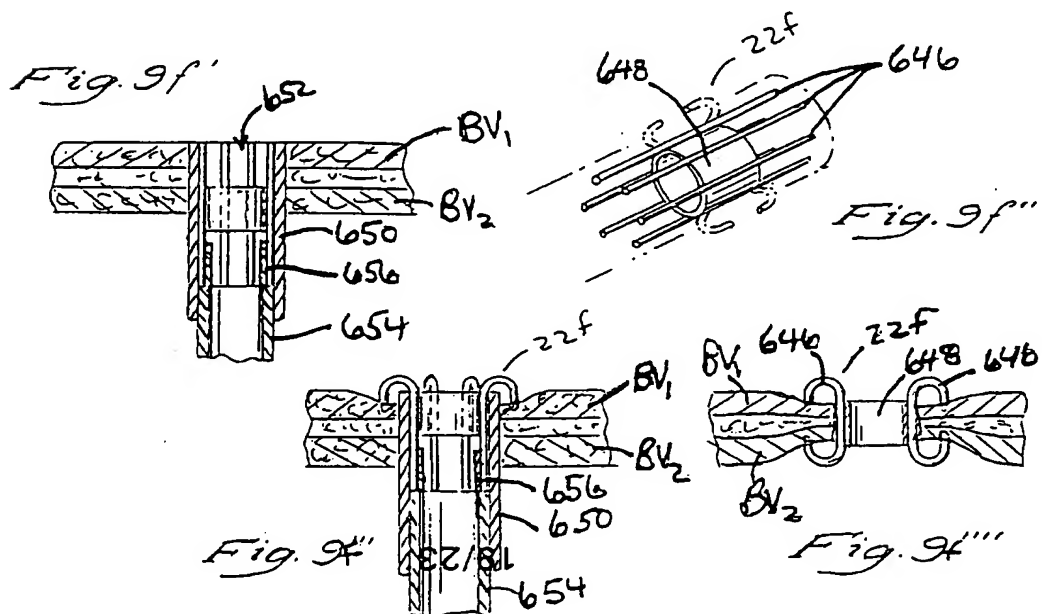
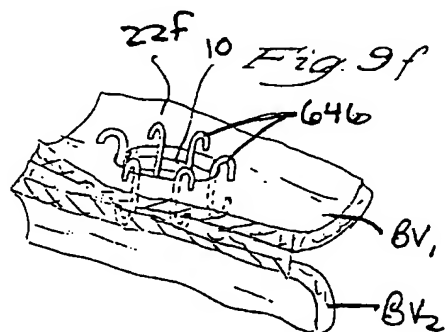
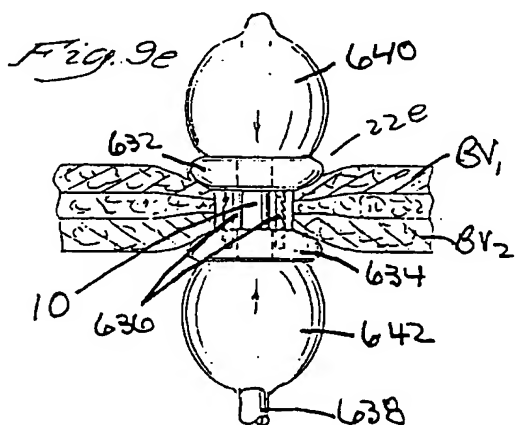
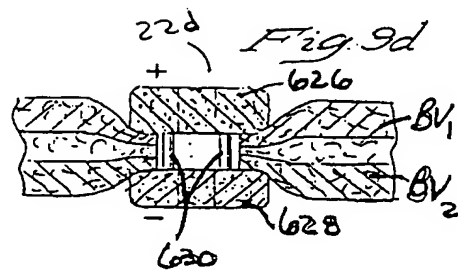
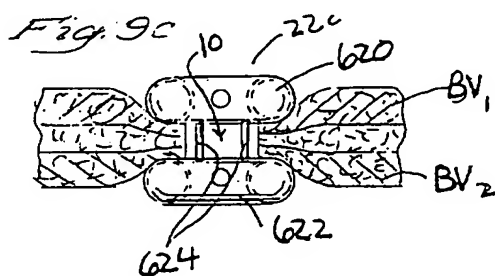


Fig. 13e





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Fig. 11a

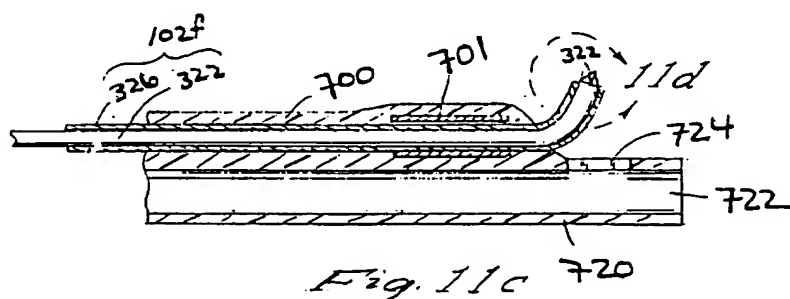
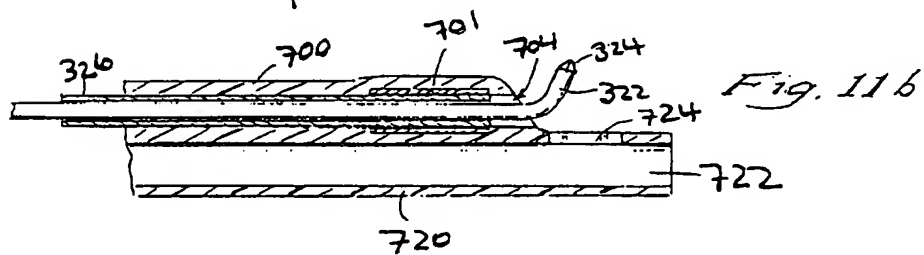
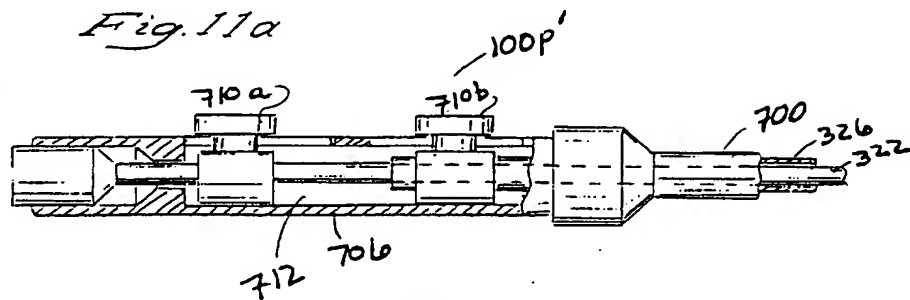


Fig. 11c

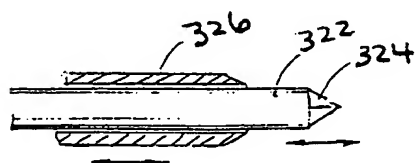
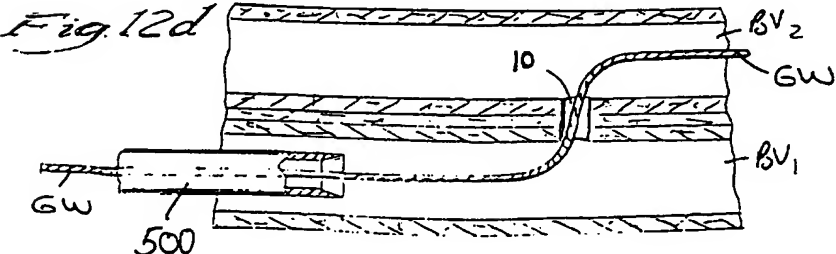
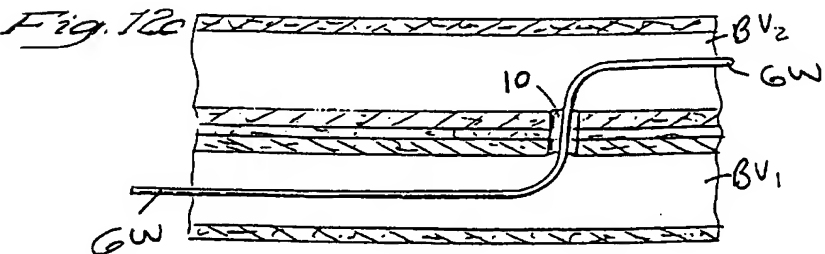
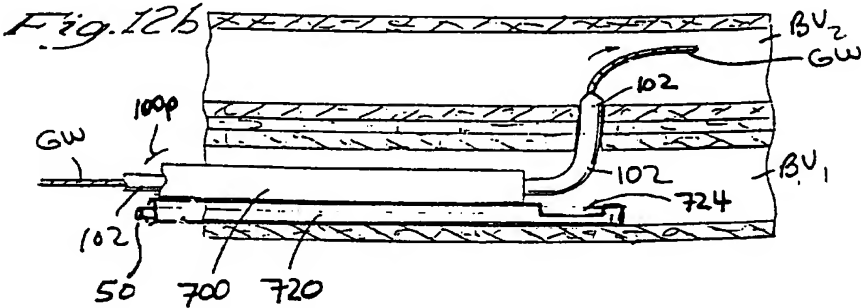
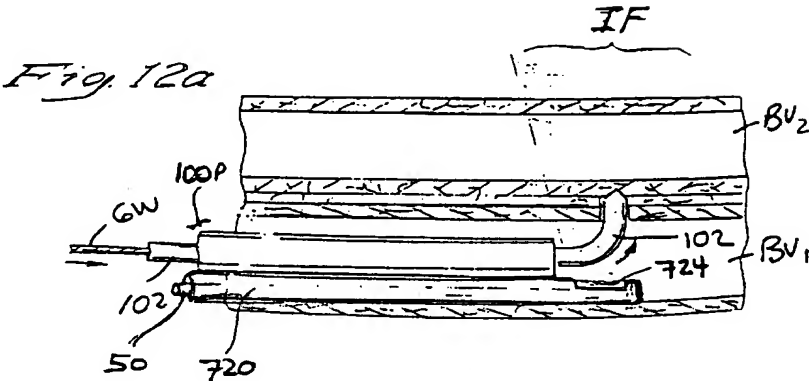
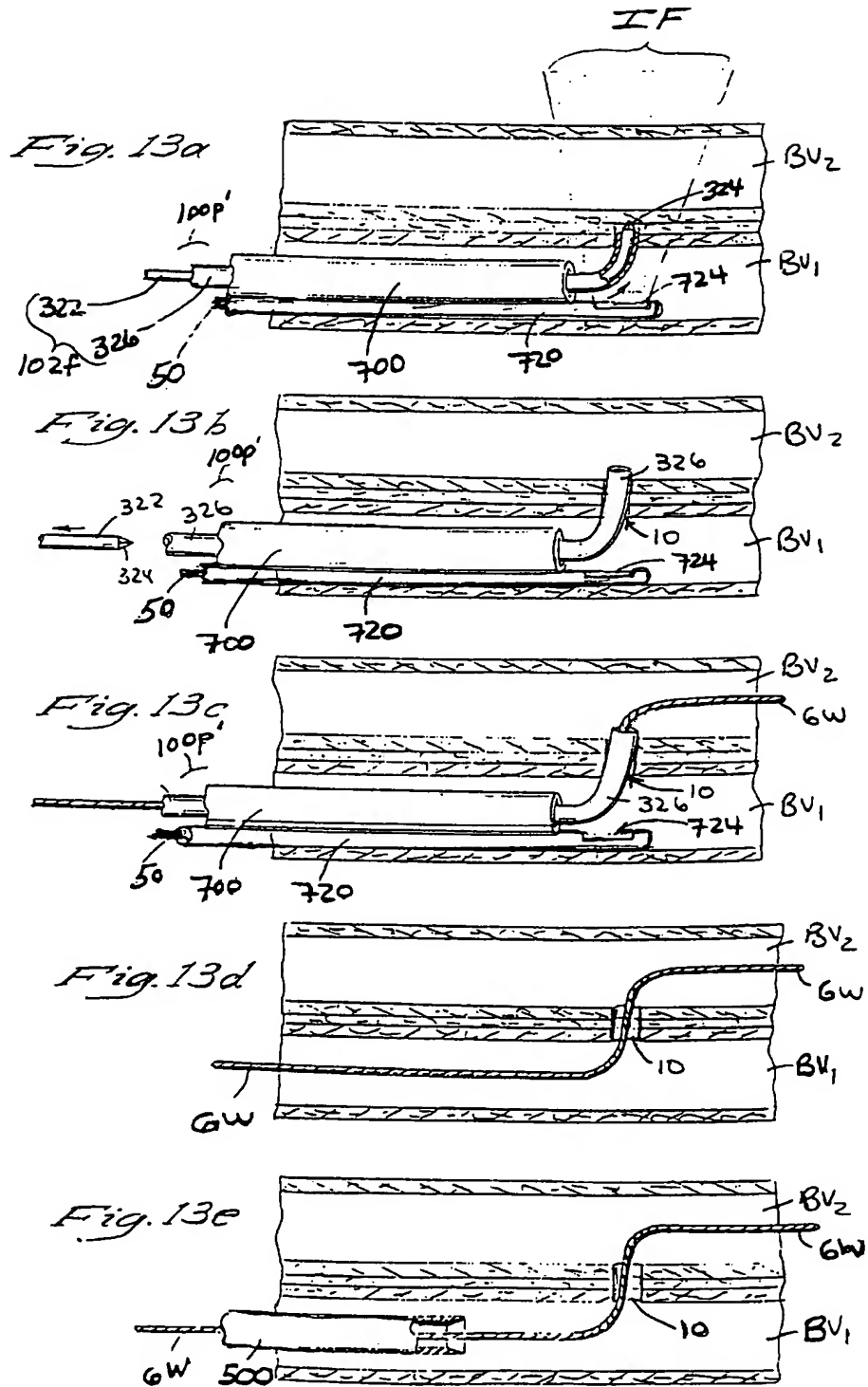


Fig. 11d



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# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US96/16483

<b>A. CLASSIFICATION OF SUBJECT MATTER</b>																				
IPC(6) : A61B 17/00 US CL : 128/898 According to International Patent Classification (IPC) or to both national classification and IPC																				
<b>B. FIELDS SEARCHED</b>																				
Minimum documentation searched (classification system followed by classification symbols) U.S. : 128/898; 606/151-156, 184-186, 194; 607/115-122; 623/001, 002																				
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched																				
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) APS																				
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>																				
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.																		
Y	US 5,456,694 A (MARIN et al) 10 October 1995, entire document.	32-87																		
A	US 5,452,733 A (STERMAN et al) 26 September 1995, entire document.	1-31																		
A	US 5,443,497 A (VENBRUX) 22 August 1995, entire document.	1-57, 87																		
A	US 5,389,096 A (AITA et al) 14 February 1995, entire document.	1-92																		
A	US 5,061,245 A (WALDVOGEL) 29 October 1991, entire document.	60-86																		
Y	US 5,456,714 A (OWEN) 10 October 1995, entire document.	88-92																		
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.																				
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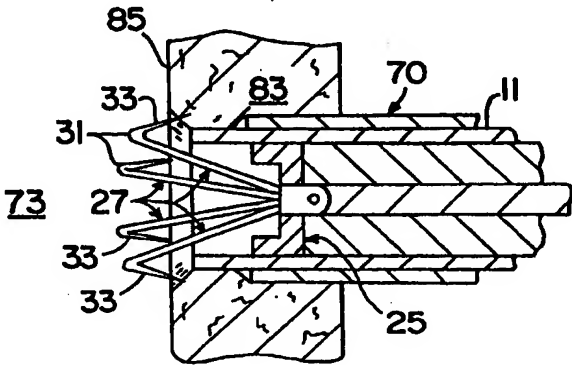
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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			(43) International Publication Date: 6 March 1997 (06.03.97)
(21) International Application Number: PCT/US95/10625 (22) International Filing Date: 24 August 1995 (24.08.95)  (71)(72) Applicant and Inventor: YOON, InBae [US/US]; 2101 Highland Ridge Drive, Phoenix, MD 21131 (US).  (74) Agent: EPSTEIN, Robert, H.; Epstein, Edell & Retzer, Suite 220, 1901 Research Boulevard, Rockville, MD 20850 (US).			(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  Published With international search report.
(54) Title: SUTURE TIE DEVICE SYSTEM AND METHOD FOR SUTURING ANATOMICAL TISSUE PROXIMATE AN OPENING			
(57) Abstract			
<p>An applicator (10) for suturing openings such as puncture sites in anatomical tissue (83) applies a suture tie device having at least two outwardly turned hooks to penetrate the tissue proximate the opening. A stem (23) and a plurality of legs (27) extending distally and radially outward from the stem, support the hooks (33) and together with a collar (25) movable along the stem and legs allow the hooks to be gathered radially inward after penetrating the tissue. The suture tie device can be disposed within a tubular housing (11) dimensioned to fit within an endoscopic portal or cannula (70) or for insertion directly through the opening in the anatomical cavity. A rod (17) is disposed within the housing and connected to a proximal end of the stem of the suture tie device. An elongate tubular member (19) is disposed between an inner circumference of the tubular housing and the rod proximally of the collar to move the collar along the stem and to gather the plurality of legs radially inward.</p>			
			

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Suture Tie Device System and Method for  
Suturing Anatomical Tissue Proximate an Opening

BACKGROUND OF THE INVENTION

Field of the Invention:

The present invention relates generally to medical procedures and instruments and, more particularly, to a suture tie device system and method for suturing anatomical tissue proximate an opening.

Description of the Background Art:

Endoscopic and minimally invasive medical procedures, such as laparoscopy, have become widely accepted for surgery and diagnosis due to the associated advantages relating to reduced trauma and hospitalization time. The performance of an endoscopic procedure, however, requires the creation of one or more puncture sites through a wall of an anatomical cavity to permit introduction of instruments such as portal sleeves or cannulas, endoscopes, ligating appliers, forceps, cauteries and the like into the anatomical cavity. The puncture sites are normally created by means of a penetrating instrument including an obturator, such as a trocar, disposed within a portal sleeve such that, after the penetrating instrument has penetrated into the anatomical cavity, the obturators are withdrawn leaving the sleeves in place to form portals in the cavity wall. Once the endoscopic procedure has been completed, the sleeves are withdrawn and the puncture sites are closed.

Herniation through an improperly closed puncture site in the wall of an anatomical cavity is one of the rare postoperative complications associated with endoscopic procedures that can lead to significant morbidity. With the increased use of endoscopic procedures and the use of larger endoscopic portals an increase in the incidence of such complications can be expected. Even where a defect is small, there is still the possibility of small bowel entrapment in a Richter's type hernia at the site of introduction of the trocar or other penetrating instrument. Hence, it is important that the puncture site be closed or approximated following removal of the endoscopic instruments.

While complications such as herniation and small bowel entrapments can be avoided by suture of the puncture site in the cavity wall, this involves a time consuming and trauma causing procedure whereby the defect in the cavity wall is enlarged and manipulated to provide access for performing suturing of the interior layers, such as the fascia, using standard curved suturing needles and strands of suture material.

Additionally, in other medical procedures, such as anastomosis, bladder reattachment and repair of congenital or non-congenital defects in the wall of an anatomical cavity such as the abdomen, bowel, small blood vessels such as veins and arteries, epidural, pleural and subarachnoid spaces, heart ventricles and spinal and synovial cavities, it is important to quickly and securely repair the opening or separation in the anatomical tissue. In minimally invasive procedures in particular, suturing of the anatomical tissue is both time-consuming and difficult as the suture needles and strands of suture material must be grasped using instruments and manipulated remotely from the operative site through narrow cannulas or sleeves.

SUMMARY OF THE INVENTION

Accordingly, it is a primary object of the present invention to overcome the above mentioned disadvantages of the prior art and to provide a suture tie device having at least two outwardly turned hooks for penetrating anatomical tissue proximate an opening to facilitate repair of the opening by capturing the tissue held by the hooks.

It is another object of the present invention to carry the outwardly turned hooks of the suture tie device on a single leg having a collar movable on the leg in the direction of sharp tissue penetrating tips of the hooks to capture tissue therebetween.

A further object of the present invention is to carry the outwardly turned hooks of the suture tie device on a plurality of radially diverging legs having a collar movable on the legs in the direction of sharp tissue penetrating tips of the hooks to gather the legs and tissue held in the hooks radially inward.

It is yet another object of the present invention to configure the collar and each leg of a suture tie device having at least two outwardly turned hooks to permit distal movement of the collar and to inhibit proximal movement of the collar.

An additional object of the present invention is to form one or more recesses on a distal face of a collar of a suture tie device having at least two outwardly turned hooks to engage sharp tissue penetrating tips of the hooks to form suture loops.

It is still another object of the present invention to provide a variety of applicators for positioning and applying the suture tie device of the present invention.

A further object of the present invention is to penetrate anatomical tissue proximate an opening with sharp tissue penetrating tips of at least two outwardly turned hooks and to capture tissue between the hooks and a collar movable in the direction of the sharp tissue penetrating tips.

Some of the advantages of the suture tie device system and method of the present invention are that the suture tie applicator can be positioned within an anatomical cavity through a cannula or portal sleeve, for example to access an inner surface of a cavity wall surrounding a puncture site, anatomical tissue proximate an opening can be sutured together more rapidly than with standard suturing needles and strands of suture material and without further enlargement or extension of the opening, the suture tie device can be made of bioabsorbable materials and left in the body thereby obviating the need for any subsequent removal procedures, the tension for approximating the tissue proximate the opening can be controlled to facilitate the healing process, and in the case of puncture site closure the possibility of scarring, herniation and other complications is reduced.

The present invention is generally characterized in a suture tie device for suturing anatomical tissue proximate an opening including at least two outwardly turned hooks having sharp tissue penetrating tips, leg means for supporting the outwardly turned hooks, and a collar selectively displaceable along the leg means in the direction of the sharp tissue penetrating tips. The leg means can be a single leg having a proximal portion and distal portion terminating in at least two outwardly turned hooks or a plurality of radially diverging legs each having an outwardly turned distal portion defining one or more of the outwardly turned hooks. The collar has a central opening configured to receive the legs and a plurality of engaging members are formed along at least a portion of an exterior surface of each leg and along an inner surface of the opening to permit distal movement of the collar while inhibiting proximal movement. One or more recesses can be formed in the collar to receive the sharp tissue penetrating tips of the hooks and can be formed with curved walls to cam the tips radially inward.

A further aspect of the present invention is characterized in an applicator for use in applying the suture tie device to anatomical tissue including an elongate tubular housing having a proximal portion and a distal portion for holding the suture tie device, leg controlling means coupled with a proximal end of the legs for controlling proximal and distal movement of the legs, and collar displacing means for selectively displacing the collar along the legs toward the tissue penetrating tips of the hooks.

Another aspect of the present invention is characterized in a method for suturing anatomical tissue proximate an opening including the steps of positioning within the opening a suture tie device with leg means for supporting at a distal end at least two outwardly turned hooks having sharp tissue penetrating tips, penetrating tissue proximate the opening with the sharp tissue penetrating tips of the outwardly turned hooks and moving a collar distally along the leg means towards the sharp tissue penetrating tips of the hooks to capture the tissue held therebetween.

Other objects and advantages of the present invention will become apparent from the following description of the preferred embodiments taken in conjunction with the accompanying drawings wherein like parts in each of the several figures are identified by the same reference characters.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a side view, partly in section, of an applicator for application of the suture tie devices of the present invention.

Fig. 2 is an exploded view of the applicator of Fig. 1.

Fig. 3 is an enlarged side view, partly in section, of the suture tie device shown in Figs. 1 and 2.

Fig. 4 is a frontal view of the suture tie device of Fig. 3.

Fig. 5 is a side view, partly in section, and Figs. 6 - 10 are broken views, partly in section, illustrating use of the applicator of Fig. 1 for applying a suture tie device to close a puncture site.

Fig. 11 is a side view of a modified suture tie device according to the present invention.

Fig. 12 is a side view of another suture tie device according to the present invention.

Fig. 13 is a side view of yet another suture tie device according to the present invention.

Figs. 14 - 17 are fragmentary views, partly in section, illustrating use of the suture tie device of Fig. 13.

Fig. 18 is an enlarged frontal view of a collar for use in a suture tie device according to the present invention.

Fig. 19 is a fragmentary view, partly in section, of the collar of Fig. 18 engaging legs of a suture tie device according to the present invention.

Fig. 20 is a fragmentary side view of the proximal end of the applicator of Fig. 1 showing scale markings on the elongate tubular sleeve.

Fig. 21 is a sectional view of the proximal end of a modified applicator according to the present invention.

Fig. 22 is a side view of the applicator of Fig. 23.

Fig. 23 is a side view, partly in section, of the proximal end of another modified applicator according to the present invention.

#### DESCRIPTION OF THE PREFERRED EMBODIMENTS

The suture tie device and applicator of the present invention can be utilized to suture closed any type of opening in biological tissue; and, accordingly, while the suture tie device and applicator are described hereinafter for use in closing a puncture site opening after endoscopic procedures, such as laparoscopy, the suture tie device and applicator can also be used to perform anastomosis, reconstructive surgery such as bladder reattachment or to repair a hernia or ruptured bowel or any other congenital or non-congenital separation between tissue segments or openings in a wall of an anatomical cavity, such as the abdomen, small blood vessels such as veins and arteries, epidural, pleural and subarachnoid spaces, heart ventricles and spinal and synovial cavities.

An applicator 10 for applying a suture tie device 12 according to the present invention, as illustrated in Figs. 1 and 2, includes a tubular housing 11 having open proximal and distal ends 13 and 15, with the suture tie device 12 being disposed within the housing 11 adjacent the open distal end 15, a slender rod 17 connected to a proximal end of the suture tie device 12 and protruding from the proximal end 13 of the tubular housing 11, and an elongated tubular sleeve 19 slidably disposed within the annular region between the inner circumferential surface of the housing 11 and the outer surface of the slender rod 17. The tubular housing 11 is preferably made of a hollow, cylindrical length of stainless steel or other suitable, medically acceptable, plastic or metal material and can be rigid, semi-rigid or flexible and transparent or opaque. An outwardly extending annular flange 21 is formed near the proximal end 13 of the housing 11 and is configured to provide a finger grip for grasping the housing 11. The outer diameter of the tubular housing 11 is dimensioned to allow passage of the housing 11 through a cannula or an incision into anatomical cavities ranging in size from the abdomen to small blood vessels, such as veins and arteries,

as well as epidural, pleural and subarachnoid spaces, heart ventricles and spinal and synovial cavities.

As best seen in Figs. 3 and 4, the suture tie device 12 includes a cylindrical stem 23 of relatively large diameter surrounded by a collar 25 and carrying four legs 27 of diminished diameter. Each leg 27 branches distally and radially outward from the stem 23 and has a shaft-like proximal end 29 connected to the stem 23 at a radially divergent angle and an acutely bent distal end 31 terminating in a sharp tissue penetrating tip 33. The bent distal end 31 of each leg 27 forms an outwardly turned hook defining a tissue receiving space 35 with an open side facing proximally toward the collar 25. The legs 27 are arranged symmetrically about the longitudinal axis 37 of the stem 23 to position pairs of tissue penetrating tips 33 at diametrically opposed locations and are preferably configured to form a circular cross-section when gathered together. The stem 23 and legs 27 are completely or partially formed of a bioabsorbable or non-bioabsorbable material, or a combination thereof, which is provided with appropriate physical characteristics so as to be entirely or partially flexible or resilient.

The collar 25 is a solid circular cylinder having an outer diameter to fit within the tubular housing and a central opening or bore 39 configured to slide over the stem 23 and legs 27 in a distal direction to gather the legs 27 radially inward. A concentric cylindrical recess 41 is formed on the distal face 43 of the collar 25 to define a space for receiving the sharp tissue penetrating tips 33 of the legs 27 when gathered. The diameter of the cylindrical recess 41 corresponds approximately to the distance between diametrically opposed tissue penetrating tips 33 of the suture tie device 12 in a gathered state (i.e., with the collar 25 displaced distally forward). The collar 25 is preferably formed as a rigid or semi-rigid member with the central opening 39 extending therethrough longitudinally and having an internal configuration or luminal surface that is

configured to cooperate with a plurality of angled teeth or ribs 45 protruding from the outer surface of the stem 23 and legs 27 such that the collar 25 is selectively displaceable only distally, in the direction of the sharp tissue penetrating tips 33 of the legs 27. Individual suture tie devices which make use of a locking/tying member configured to cooperate with a plurality of angled teeth on a leg member are described in U.S. Patent No. 5,100,418 to Yoon, which is incorporated herein by reference.

The suture tie device 12 is oriented within tubular housing 11 as shown in Figs. 1 and 2, such that the sharp tissue penetrating tips 33 of the legs 27 face away from distal opening 15 toward collar 25. The radial divergence and length of the legs 27 in the suture tie device 12 are selected so that, together with the radius of curvature of the acutely bent distal end 31, the distance between diametrically opposed tissue penetrating tips 33 of the legs 27 is greater than the outside diameter of the tubular housing 11. Owing to the elasticity of the material used to fabricate the legs 27, confinement of the suture tie device 12 within the tubular housing 11 creates an outward radial bias in the legs 27, such that if the suture tie device 12 is advanced distally relative to tubular housing 11 so as to protrude from the open distal end 15 of the housing 11, the legs 27 will expand radially outward. In other words, the specific configuration of the legs 27 is chosen such that the radial distance from the stem 23 to the sharp tissue penetrating tips 33 of the legs 27 (i.e., the gap width of each hook) is, in a relaxed state, greater than the outer radius of the tubular housing 11.

The slender rod 17 is approximately the same diameter as the stem 23 and has a distal end 47 adapted to couple with the proximal end 49 of the stem 23. The coupled ends 47 and 49 of the rod 17 and stem 23, respectively, are held together with a bio-absorbable frangible pin 51 or by any other medically-acceptable means suitable for releasably connecting the two elements so that the position of the

suture tie device 12 can be controlled by manipulation of the rod 17 and the rod 17 withdrawn once the suture tie device 12 is placed in anatomical tissue. The rod 17 extends from the proximal end 49 of the stem 23 to protrude from the proximal end 13 of the tubular housing 11 and terminates proximally in a pair of radially extending arms 53.

The tubular sleeve 19 fits telescopically within the tubular housing 11 to coaxially surround the rod 17 and has a distal face 55 for abutting the proximal face 57 of the collar 25 and a pair of elongated slots 59 defined longitudinally at a proximal end 61 to receive the radial arms 53 of the rod 17. The proximal end 61 of the tubular sleeve 19 is also threaded on an exterior surface 63 to couple with the internal threads 67 of a circular endcap 65. A spring 69 is held in compression between the end cap 65 (which closes the proximal end 61 of the tubular sleeve 19) and the radial arms 53 of rod 17 to bias the proximal end of the rod 17 towards a distalmost position within the elongated slots 59. The distal bias inhibits unintentional proximal movement of the rod 17 and thus maintains the position of the suture tie device 12 relative to the tubular sleeve 19.

The rod 17 and tubular sleeve 19 are preferably made of stainless steel or other suitable, medically acceptable, plastic or metal materials and can be rigid, semi-rigid or elastic. Additionally, all of the foregoing components except the suture tie device 12 can be disposed after use or disassembled for sterilization and reuse.

The applicator 10 can be employed directly through a puncture site opening or in combination with a portal sleeve to close the puncture site opening. For purposes of illustration, use of the applicator 10 will be described in combination with a portal sleeve inserted into an anatomical cavity through a puncture in the cavity wall formed by a penetrating member, such as a trocar. Fig. 5 shows a portal sleeve 70 having an open distal end 71 positioned within an

anatomical cavity 73 and an open proximal end 75 secured to a portal housing 77 externally of the cavity 73. The applicator 10 is inserted into the portal housing 77 through an opening 79 defined in a rear wall 81 of the portal housing 77. The tubular housing 11 of the applicator 10 slides through the portal housing 77 and the portal sleeve 70 into the anatomical cavity 73 as shown in Fig. 6. During the insertion procedure, suture tie device 12 is disposed completely within tubular housing 11 and the legs 27 thereof drawn radially inward owing to the presence of tubular housing 11.

With distal end 15 of tubular housing 11 positioned within anatomical cavity 73, portal sleeve 70 is retracted proximally until almost flush with an inner surface 85 of the cavity wall 83 (e.g., adjacent the peritoneum 87). Tubular housing 11 is also retracted proximally a predetermined distance by exerting a proximal force on the annular flange 21 of the housing 11 while holding the endcap 65 stationary to expose the sharp tissue penetrating tips 33 of the legs 27, as shown in Fig. 7. This can be accomplished, for example, by placing index and middle fingers of one hand on opposite sides of the tubular housing 11 ahead of the annular flange 21 and using the thumb of the hand to hold the endcap 65 stationary while drawing the flange 21 toward the endcap 65. In this manner, the suture tie device 12 is not appreciably moved in either proximal or distal directions.

In the deployed position, the legs 27 of the suture tie device 12 spring radially outward due to elastic energy which is stored during their confinement within tubular housing 11. The sharp tissue penetrating tips 33 of the legs 27 extend radially outward and face proximally toward the distal surface 85 of the tissue surrounding the puncture site at a number of locations circumscribing the puncture site opening.

Referring now to Fig. 8, the entire applicator 10 is retracted proximally to cause the proximally-facing, sharp

tissue penetrating tips 33 of the legs 27 to penetrate into the cavity wall 83. The amount of penetration depends on the length of the tissue penetrating tips 33 (i.e., the depth of the throat of each hook), and suture tie devices of various lengths can be chosen according to the type of cavity penetrated, the specific layers to be closed or approximated, and the amount of fat and muscle tissue present. Along with the length of the tissue penetrating tips 33 of the legs 27, the radius of curvature of the acutely bent distal end 31 of the legs 27 determines how much tissue of the cavity wall 83 is received in the hook formed by each leg 27.

Once the tissue penetrating tips 33 of the legs 27 are positioned in the cavity wall 83, tubular housing 11 and portal sleeve 70 are retracted while the legs 27 and thus the sharp tissue penetrating tips 33 of the legs 27 are gathered radially inward as shown in Fig. 9. This is accomplished, for example, by positioning the index and middle fingers of the hand on opposite sides of the tubular sleeve 11 immediately ahead of the protruding radial arms 53 of the rod 17 and pressing down on the endcap 65 with the thumb of the hand to urge the tubular sleeve 19 and thus the collar 25 distally over the stem 33 and legs 27 of the suture tie device 12 toward the sharp tissue penetrating tips 33. Angled teeth or ribs 45 (see Fig. 3) on the stem 23 and legs 27 prevent proximal movement of the collar 25 so that, once advanced, collar 25 will not loosen. The displacement of the collar 25 along legs 27 controls the tension applied to the tissue surrounding the puncture site to approximate the anatomical tissue adjacent the opening.

The collar 25 is preferably advanced distally until the sharp tissue penetrating tips 33 of the legs 27 are received in the cylindrical recess 41 on the distal face 43 of the collar 25 forming closed loops holding the tissue which has been gathered. With the collar 25 properly positioned, the rod 17 is released from the stem 23 using a quick tug to break the frangible pin 51 that holds the two together or by

any other suitable method of release. Fig. 10 shows an implanted suture tie device 12 within the wall 83 of the anatomical cavity 73. After implantation of the suture tie device 12 to approximate the inner layers ( e.g., the peritoneum, muscle and fascial layers 87, 89 and 91 in Fig. 5) of the cavity wall 83, the outer skin layer (element 93 in Fig. 5) can be sutured in the conventional manner and the suture tie device 12 left for absorption by the body over time.

A modification of the suture tie device 12 is illustrated in Fig. 11 wherein the modified suture tie device 112 includes a stem 123 from which three legs 127 extend distally and radially outward like a tripod. The legs 127 are the same as legs 27 previously described and each have a proximal end 129 connected to the stem 123 at an angle and an acutely angled distal end 131 terminating in a sharp tissue penetrating tip 133 extending proximally and radially outward. While the tissue penetrating tips 33 of suture tie device 12 reside essentially in two perpendicular planes in their distended state, the tissue penetrating tips 133 of suture tie device 112 preferably lie within three oblique planes. Like suture tie device 112, the stem 123 and legs 127 of suture tie device 112 are also formed with angled teeth 145 or the like to couple with a cooperating structure in collar 125 to inhibit proximal movement of the collar 125 while allowing distal movement.

Another modification of the suture tie device 12 is illustrated in Fig. 12 with the primary difference being a reduced number of legs. The modified suture tie device 212 includes only two legs 227 which are essentially coplanar and diverge radially from one another in a distal direction before bending acutely backward at a distal end 231 and terminating in sharp tissue penetrating tips 233. The legs 227, stem 223 and collar 225 of suture tie device 212 are essentially the same as the legs 127, stem 123 and collar 125 of suture tie device 112 and the legs 27, stem 23 and collar 25 of suture tie device 12, and are each provided

with angled teeth 245 or the like to prevent proximal movement of the collar 225. Hence, suture tie devices 112 and 212 can be directly substituted for suture tie device 12 in the applicator 10 of the present invention.

In a further modification of the suture tie device of the present invention, shown in Fig. 13, the modified suture tie device 312 has a single rigid or semi-rigid leg 327 extending distally from stem 323 and a collar 325 with an annular camming recess 341. The single leg 327 is the same diameter as the stem 323 and branches outward at a distal end 330 into two bent portions or knees 331 from which sharp tissue penetrating tips 333 extend. The collar 325 is configured to fit within tubular housing 11 and has a distal face 343 defining the annular recess 341 with curved sidewalls 344 to form a cam surface for bending the sharp tissue penetrating tips 333 of the device; however, the initial distance between the sharp tissue penetrating tips 333 of the suture tie device 312 and the leg 327 is approximately the same as the radius of the recess 341 in the distal face 343 of the collar 325. Since the collar 325 is approximately the same diameter as the tubular housing 11 and the leg 327 is a rigid or semi-rigid member, the tissue penetrating tips 333 of the suture tie device 312 generally do not elastically and resiliently deform when confined within the housing 11.

Use of the suture tie device 312 of Fig. 13 individually for closing a puncture site is illustrated in Figs. 14 through 17 wherein only the distal end of the applicator 10 is shown and the steps for exposing the sharp tips 333 of the suture tie device 312 have been omitted; however, it will be appreciated that a similar method can be used to perform anastomosis by applying a plurality of circumferentially spaced suture ties to join abutting tubular walls of anatomical organs or vessels.

With the collar 325 retained within the tubular housing 11 externally of the cavity wall 83 and the tips 333 exposed within the anatomical cavity 73, the applicator 10 is tilted

so that one of the sharp tissue penetrating tips 333 snags tissue on one side of the puncture as shown in Fig. 14. The applicator 10 is then tilted in an opposite direction and manipulated so that the other sharp tissue penetrating tip 333 snags tissue on the opposite side of the puncture as shown in Fig. 15. The tubular housing 11 is then straightened as shown in Fig. 16 and the leg 327 retracted proximally through the collar 325 which is held stationary to pull the tissue penetrating tips 333 through the tissue and toward the collar 325. The cooperating rib and detent structure 345 of the collar 325 and leg 327 prevents the leg 327 from slipping out of the collar 325 or from loosening. As the sharp tissue penetrating tips 333 of the leg 327 move into the recess 341 formed in the collar 325, the tips 333 are cammed radially inward against the curved sidewalls of the recess 341, concomitantly gathering inward the tissue captured between the leg 327 and the sharp tissue penetrating tips 333 to approximate the puncture site opening. The rod 317 is then detached from the stem 323 of the suture tie device 312 in the manner previously described in connection with suture tie device 12, the proximal portion of the suture tie is clipped if desired, and the applicator 10 removed from the site.

In addition to the foregoing modifications, the plural-tipped suture tie device of the present invention can be further modified to incorporate the various aspects of the individual suture ties described in U.S. Patent No. 5,100,418 to Yoon.

A modification of the collar 25 is illustrated in Figs. 18 and 19 wherein the modified collar 425 has individual apertures or openings 439 for receiving respective legs 427 of a suture tie device 412 similar to suture tie device 12 previously described and individual recesses 441 for receiving the respective tissue penetrating tips of each leg 427. More particularly, the collar 425 has a cylindrical body 426 with a plurality of closely spaced openings 439 defined near the center of the body 426 and a plurality of

annularly spaced recesses 441 radially spaced from the openings on the distal face 443 of the collar 425. Each of the openings 439 in collar 425 is dimensioned to accommodate a single leg 427 of the suture tie device 412 and preferably have an internal configuration or luminal surface that is configured to cooperate with a plurality of angled teeth or ribs 445 protruding from the outer surface of the leg 427 extending therethrough. The collar 425 is initially positioned distally of the stem 423 of the suture tie device 412, as shown in Fig. 19, with the legs 427 of the device extending through the openings 439 in the collar 425 and the recesses 441 each facing a sharp tissue penetrating tip (not shown) of the legs 427.

The applicator 610 illustrated in Fig. 20 is similar to the applicator 101 in the embodiment of Figs. 1 and 2 with the exception that a scale 612 is marked on an outer surface of the proximal end 661 of the tubular sleeve 619. The tubular sleeve 619 is telescopically fitted within a tubular housing 611 and provided at a proximal end with elongated longitudinal slots 659 through which radial arms 653 of a slender rod (not shown) extend. The scale 612 allows the user to gauge the displacement of the radial arms 653 within the elongated slots 659 to control the displacement of a collar along the stem and legs of a suture tie device (not shown). The amount of distal displacement of the collar on the legs is directly related to the tension applied to the walls of the puncture wound. Hence, the user of the applicator 610 is able to control the tension of the suture tie device with reference to the scale 612 marked on the tubular sleeve 619.

Another modification of the applicator of the present invention is shown in Figs. 21 and 22, wherein the applicator 710 is similar to the applicator 10 and has an elongate tubular housing 711 with a reduced diameter portion 712 near a closed proximal end 713 and a rod 717 disposed completely within the housing 711. Specifically, the elongate tubular housing 711 is provided with a finger grip

721 near the proximal end 713 formed by the reduced diameter portion 712 of the tubular housing 711 to facilitate grasping of the tubular housing 711, for example with two fingers placed on opposite sides of the finger grip 721 within the reduced diameter portion 712. An elongate tubular sleeve 719 is similar to tubular sleeve 19 but has a reduced outer diameter portion 720 in the vicinity of the finger grip 721 of the tubular housing 711. The reduced diameter portion 720 of the elongate tubular sleeve 719 extends from the distal end of the finger grip 721 to the proximal end 761 of the sleeve 719, which in turn protrudes through an opening 762 in the proximal end 713 of the tubular housing 711. The rod 717 is telescopically fitted within the sleeve 719 and terminates proximally in a pair of radial arms 753 that extend perpendicularly through a pair of elongated slots 759 defined in the reduced diameter portion 720 of the elongate tubular sleeve 719 near the proximal end 761. The radial arms 753 of the rod 717 are initially positioned at the distal end 764 of the slots 759 against the closed proximal end 713 of the housing 711. Like the applicator 10, the modified applicator 710 has an endcap 765 that closes the tubular sleeve 719 at a proximal end and a spring 769 held in compression between the radial arms 753 of the rod 717 and the endcap 765. A scale 766 is also marked on the proximal end 761 of the tubular sleeve 719 to gage the advancement of a collar on the legs of a suture tie device being implanted.

Only the proximal portions of the applicator 710 have been illustrated in Figs. 21 and 22; however, it will be appreciated that the distal portions can be formed with any cooperating structure to deliver suture tie devices of the type described herein, such as that shown in Figs. 1 and 2. For purposes of illustration, reference will be made to the suture tie device of Fig. 1 when explaining operation of the applicator.

In use, the applicator 710 is positioned within a puncture site in the manner previously described in

connection with applicator 10 and index and middle fingers of the user are disposed on opposite sides of the finger gripping portion 721 and the thumb of the same hand rested on end cap 765 at the proximal end 761 of tubular sleeve 719 to slide the tubular housing 711 proximally toward end cap 765. Spring 769 exerts a force against rod 717 to prevent proximal movement of the rod 717 as the housing 711 is drawn toward the endcap 765 to expose the sharp tissue penetrating tips 33 of the suture tie device within the anatomical cavity. The entire applicator 710 is then retracted so that the tissue penetrating tips 33 of the suture tie device penetrate the tissue surrounding the puncture site. Exertion of continued pressure on end cap 765 and finger gripping portion 721 causes an inner surface of the finger gripping portion 721 to bear against the radial arms 753 of the rod 717 thereby urging the rod 717 toward the end cap 765 against the bias of spring 769. With reference to Fig. 1, distal movement of the elongate tubular sleeve 719 relative to the rod 717 causes collar 25 to displace distally along the legs 27 of the suture tie device, thereby gathering the legs 27 radially inward to approximate the anatomical tissue adjacent the puncture site opening. The tension applied to the tissue can be gaged using the scale 766 marked on the proximal end 761 of the tubular sleeve 719 and removal of the applicator 710 from the puncture site proceeds as previously described.

Yet another modification of the applicator is illustrated in Fig. 23 wherein a tubular housing 811 is similar to tubular housing 711 with the exception that the finger grip 821 is defined between a pair of longitudinally spaced annular disks 822 and 824, and is rounded to accommodate the index and middle fingers of the user, for example. A tubular sleeve 819 similar to tubular sleeve 19 is disposed within the tubular housing 811 and includes a distal portion 860 having a small diameter bore 826 corresponding approximately to the diameter of a stem portion of the suture tie device to be applied, and a

proximal portion 861 having a larger diameter bore 828. A rod 817 is disposed primarily within the small diameter bore 826 of the tubular sleeve 819 and includes an increased diameter portion 820 disposed within the large diameter bore 828 of the tubular sleeve 819. The rod 817 further includes a pair of radial protrusions 853 which project radially outward from an outer surface of the increased diameter portion 820 through slots 859 defined on opposed sides of the tubular sleeve 819 and are received in an annular cavity 862 defined on an interior surface of tubular housing 811, thereby limiting movement of tubular housing 811 relative to the rod 817 in accordance with the length of the cavity 862. A spring 896 is held in compression between a proximal face of the rod 817 and a ring handle 865 which closes the proximal end 861 of the tubular sleeve 819 to normally bias the rod 817 to a distal end of the slots 859. A scale 812 is advantageously marked on an outer surface of the tubular sleeve 819 so that the user may gauge the tension applied to the tissue of the puncture wound by the advancement of the housing 811 relative to the tubular sleeve 812.

From the above, it will be appreciated that the applicator of the present invention can be used to quickly and effectively close a puncture site opening formed by a penetrating member such as a trocar as well as to perform anastomosis, reconstructive surgery such as bladder reattachment or to repair a hernia or ruptured bowel or to suture any other opening formed in anatomical tissue or separating tissue segments. Hence, by "close" or "repair" is meant to approximate or suture together any congenital or non-congenital gaps between tissue segments such as adjacent tubular vessels or disconnected organs and holes or recesses in anatomical tissue such as bowel ruptures, hernias or puncture site openings in a cavity wall. It will also be appreciated that the applicator of the present invention can be inserted into an anatomical cavity through a cannula or portal sleeve as well as directly through an incision or puncture in the wall of an anatomical cavity.

The suture tie of the present invention can have any number of legs that are acutely bent, curved or configured in any way to form one or more tissue penetrating hooks for grasping tissue proximate a puncture site or other opening in anatomical tissue. When the suture tie of the present invention has only one leg, that leg is configured to carry at least two outwardly turned tissue penetrating hooks; and when plural legs are provided, each of the legs can carry one or more outwardly turned tissue penetrating hooks. Any one or all of the stem, proximal and distal ends of the legs, and the collar can be completely or partially formed of a bioabsorbable or non-bioabsorbable material, or a combination thereof, which can be provided with appropriate physical characteristics so as to be entirely or partially rigid, semi-rigid or flexible, elastic, resilient or malleable in accordance with the suture tie device's intended utilization.

Various bioabsorbable or biodegradable materials can be used to make the suture devices of the present invention with the composition determined by the rigidity or flexibility required. Generally, the bioabsorbable materials are thermoplastic polymers such as absorbable polymers and copolymers of poly-dioxanne, lactide, glycolide and the like. Polyglycolic acid is disclosed in U.S. Pat. Nos. 3,463,158; 3,739,773; and 3,772,420. Suitable polylactic acids are disclosed in U.S. Pat. No. 3,636,956. Examples of absorbable polyesters are shown in U.S. Pat. Nos. 3,225,766 and 3,883,901. Absorbable cellulose glycolic acid ethers are shown in U.S. Pat. No. 2,764,159. Examples of suitable esters of alpha-cyanoacrylic acid are found in U.S. Pat. Nos. 3,527,841; 3,564,078 and 3,759,264.

The throat and gap dimensions of the hooked portion each leg (i.e., the depth and width of the tissue receiving space defined by each hook) are chosen to suit the particular procedure to be performed and can be such that the sharp tip of each hook penetrates partially or completely through anatomical tissue such as an anatomical

cavity wall to mate with a collar. The collar can have any exterior shape fitting within a tubular housing and can have a continuous or discontinuous distal surface defining one or more recesses or apertures to receive the sharp tissue penetrating tips of the legs. For example, the collar could include a cylindrical body of smaller diameter than the tubular housing of the applicator with recesses being formed in a plurality of tubular members carried by the cylindrical body on radial arms. In those instances where the sharp tissue penetrating tips of the legs are to be received in individual recesses, alignment of the tips with the recesses can, for example, be achieved by providing a cooperating spline and groove arrangement between the opening in the collar and the leg or legs of the suture tie device.

The applicator can be configured to hold a single suture tie device as shown or multiple suture tie devices; and when multiple suture tie devices are to be held, the applicator can be configured in any manner suitable for holding and applying the suture tie devices, including the configurations shown and described in U.S. Patent No. 5,100,418 to Yoon. Additionally, the housing, rod and sleeve of the applicator can be rigid, semi-rigid or flexible and normally straight or curved for performing different procedures.

Inasmuch as the present invention is subject to many variations, modifications and changes in detail, it is intended that all subject matter discussed above or shown in the accompanying drawings be interpreted as illustrative only and not be taken in a limiting sense.

What Is Claimed Is:

1. A suture tie device for suturing anatomical tissue proximate an opening comprising  
at least two outwardly turned hooks having sharp tissue penetrating tips;

leg means for supporting said at least two outwardly turned hooks; and

a collar selectively displaceable along said leg means in the direction of said sharp tissue penetrating tips.

2. A suture tie device as recited in claim 1 wherein said leg means is a single leg having a proximal portion and a distal portion terminating in said at least two outwardly turned hooks.

3. A suture tie device as recited in claim 2 wherein said collar has a central opening configured to receive said leg and a plurality of engaging members are formed along at least a portion of an exterior surface of said leg and along an inner surface of said opening to permit distal movement of said collar and to inhibit proximal movement of said collar.

4. A suture tie device as recited in claim 3 wherein at least one recess is formed in said collar to receive said sharp tissue penetrating tips of said outwardly turned hooks.

5. A suture tie device as recited in claim 4 wherein said recess is an annular cavity formed on a distal face of said collar surrounding said central opening.

6. A suture tie device as recited in claim 5 wherein said annular cavity is defined by inwardly curved walls to cam said sharp tissue penetrating tips of said outwardly turned hooks inward.

7. A suture tie device as recited in claim 4 and further comprising a plurality of recesses formed in said collar to receive said sharp tissue penetrating tips of said outwardly turned hooks.

8. A suture tie device as recited in claim 1 wherein said leg means includes a plurality of legs each having an outwardly turned distal portion defining one or more of said outwardly turned hooks.

9. A suture tie device as recited in claim 8 and further comprising a cylindrical stem having a distal end from which said legs extend distally and radially outward.

10. A suture tie device as recited in claim 9 wherein said collar defines a central opening for receiving said stem and legs and a plurality of engaging members are formed along at least a portion of an exterior surface of said stem and legs and along an inner surface of said opening to permit distal movement of said collar from said stem onto said legs to gather said plurality of legs radially inward.

11. A suture tie device as recited in claim 10 wherein a recess is formed on a distal face of said collar to receive said sharp tissue penetrating tips of said outwardly turned hooks.

12. A suture tie device as recited in claim 11 wherein said recess is a cylindrical cavity.

13. A suture tie device as recited in claim 8 wherein said collar defines a plurality of openings each of which is configured to receive one of said legs.

14. A suture tie device as recited in claim 13 wherein said legs extend distally and radially outward from said plurality of openings and a plurality of engaging members

are formed along at least a portion of an exterior surface of said legs and along respective inner surfaces of said openings to permit distal movement of said collar on said legs to gather said plurality of legs radially inward.

15. A suture tie device as recited in claim 1 wherein at least a portion of said outwardly turned hooks, leg means and collar are made of a bioabsorbable material.

16. An applicator in combination with a suture tie device, the applicator being applicable for use in applying the suture tie device to anatomical tissue, the suture tie device having at least two outwardly turned hooks emanating from at least one leg and a collar movable along the leg toward sharp tissue penetrating tips of the outwardly turned hooks, the applicator comprising

an elongate tubular housing having a proximal portion and a distal portion for holding the suture tie device;

leg controlling means, coupled with a proximal end of said at least one leg, for controlling proximal and distal movement of said at least one leg; and

collar displacing means, abutting a proximal face of said collar, for selectively displacing said collar along said at least one leg toward said tissue penetrating tips of said hooks.

17. An applicator as recited in claim 16 wherein said collar displacing means includes an elongate tubular sleeve telescopically disposed within said tubular housing and said leg controlling means includes a rod translatably disposed within a bore defined in said elongate tubular sleeve.

18. An applicator as recited in claim 17 wherein at least one elongated longitudinal slot is formed in a proximal end of said tubular sleeve and said rod includes at

least one radially extending arm engaged in said longitudinal slot.

19. An applicator as recited in claim 18 wherein said radially extending arm is biased towards a distal end of said longitudinal slot.

20. An applicator as recited in claim 19 wherein said tubular sleeve protrudes from a proximal end of said housing and said elongate tubular housing includes a finger grip defined near a proximal end of said housing to facilitate grasping.

21. An applicator as recited in claim 20 wherein said finger grip is an outwardly extending flange.

22. An applicator as recited in claim 20 wherein said finger grip is a reduced diameter portion defined near a proximal end of said elongate tubular housing to facilitate grasping.

23. An applicator as recited in claim 20 wherein said finger grip is defined by a pair of longitudinally spaced, outwardly extending flanges provided near a proximal end of said elongate tubular housing to facilitate grasping.

24. An applicator as recited in claim 20 wherein said rod and radial arm protrude from a proximal end of said tubular housing.

25. An applicator as recited in claim 24 and further comprising a scale marked on a proximal portion of said tubular sleeve in the vicinity of said longitudinal slot to indicate an extent of movement of said rod relative to said tubular sleeve.

26. An applicator as recited in claim 22 wherein said tubular sleeve includes a reduced diameter proximal portion extending proximally through said reduced diameter portion of said elongate tubular housing.

27. An applicator as recited in claim 26 wherein the proximal end of said housing is closed around said reduced diameter portion of said sleeve and said rod terminates proximally between said reduced diameter portion of said housing and said closed proximal end of said housing.

28. An applicator as recited in claim 27 and further comprising a scale marked on a proximal portion of said tubular sleeve in the vicinity of said longitudinal slot to indicate an extent of movement of said rod relative to said tubular sleeve.

29. An applicator as recited in claim 23 wherein an increased diameter bore portion is defined in a proximal end of said tubular sleeve and said rod includes an increased diameter portion which is disposed within said increased diameter bore portion of said tubular sleeve.

30. An applicator as recited in claim 29 wherein at least one longitudinally extending cavity is defined in an inner wall of said elongate tubular housing near a proximal end to receive said at least one radial arm of said rod.

31. An applicator as recited in claim 30 wherein a scale is marked on a proximal portion of said tubular sleeve to indicate an extent of movement of said rod relative to said tubular sleeve.

32. An applicator as recited in claim 25 wherein said at least one leg of said suture device and said rod are coupled with a frangible, bioabsorbable pin.

33. A method of suturing anatomical tissue proximate an opening comprising the steps of

positioning within the opening a suture tie device with leg means for supporting at a distal end at least two outwardly turned hooks having sharp tissue penetrating tips; penetrating tissue proximate the opening with said sharp tissue penetrating tips of said outwardly turned hooks; and

moving a collar distally along the leg means towards the sharp tissue penetrating tips of the hooks.

34. A method of suturing anatomical tissue as recited in claim 33 wherein said leg means includes a plurality of distally and radially extending legs and further comprising, after said penetrating step, the step of gathering said plurality of legs radially inward.

35. A method of suturing anatomical tissue as recited in claim 33 and further comprising, after said moving step, the step of capturing said sharp tissue penetrating tips of said hooks within one or more recesses formed in said collar.

36. A method of suturing anatomical tissue as recited in claim 35 and further comprising, after said capturing step, the step of camming said sharp tissue penetrating tips of said hooks radially inward against curved surfaces of said one or more recesses.

37. A method of suturing anatomical tissue as recited in claim 33 wherein said positioning step includes inserting a tubular housing having a proximal end and a distal end holding the suture tie device through an opening in anatomical tissue and retracting said elongate tubular housing relative to said suture tie device.

38. A method of suturing anatomical tissue as recited in claim 37 and further comprising, after said retracting step, the step of expanding a plurality of said legs radially outward.

39. A method of suturing anatomical tissue as recited in claim 36 and further comprising, before said positioning step, the step of creating a puncture site opening in the wall of an anatomical cavity.



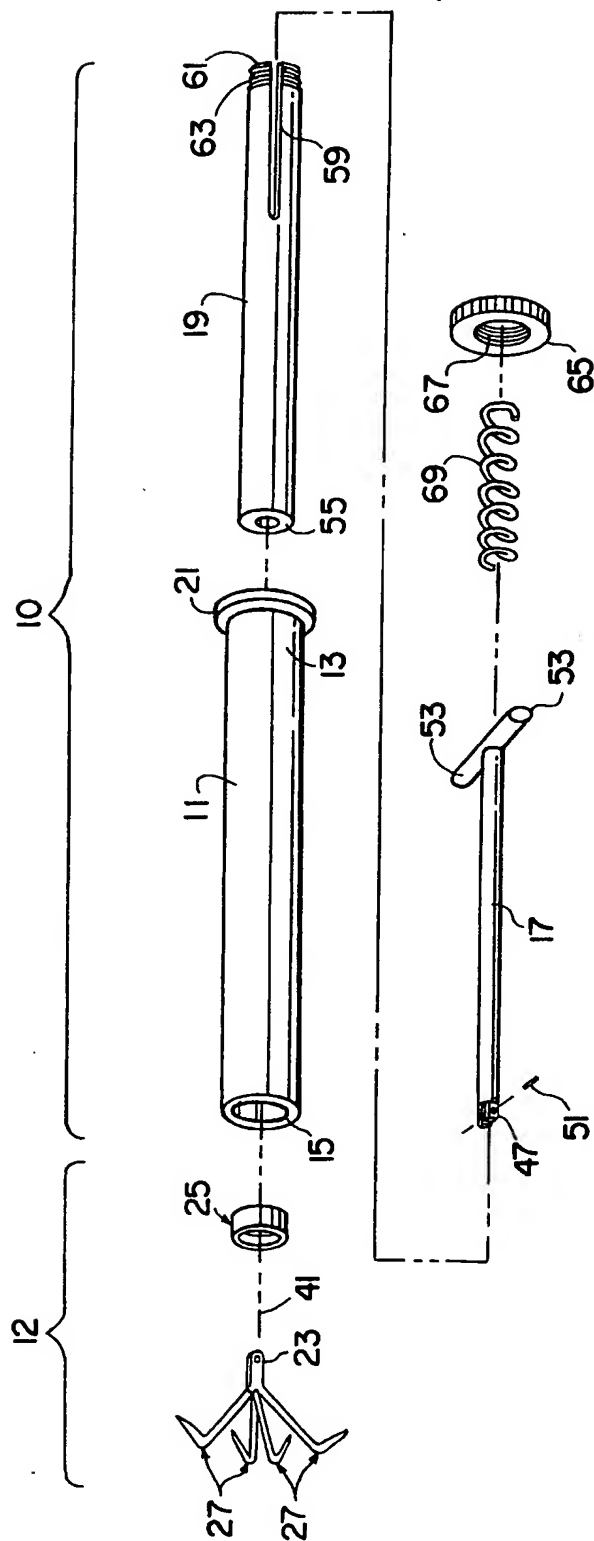


FIG. 2

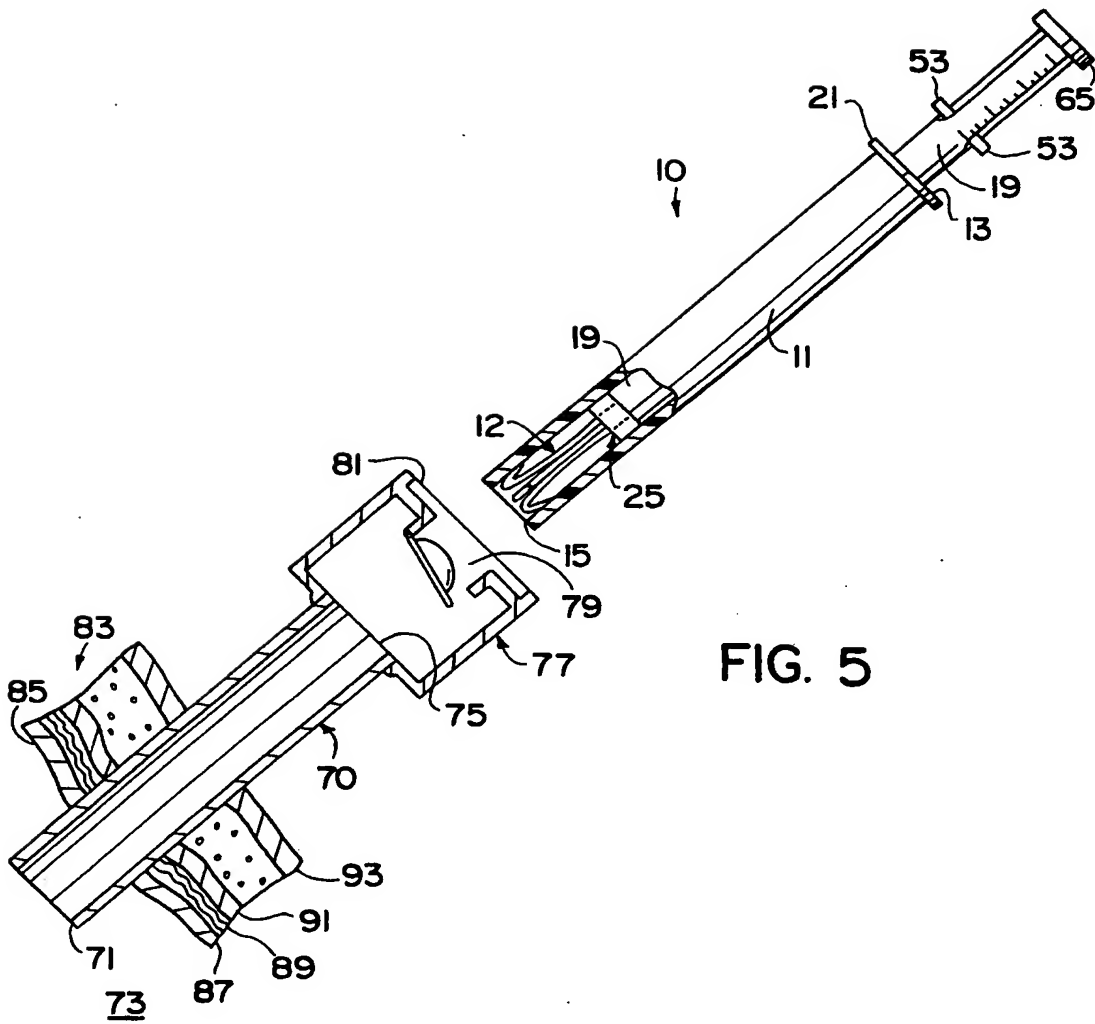


FIG. 5

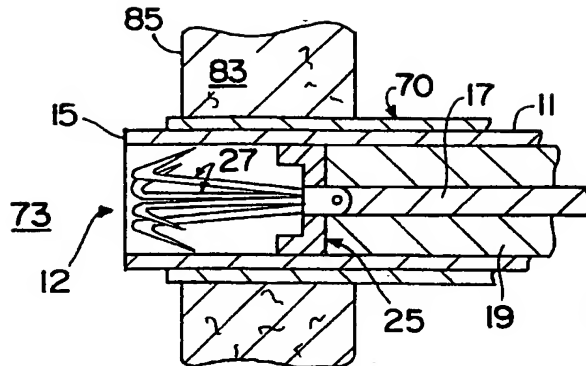


FIG. 6

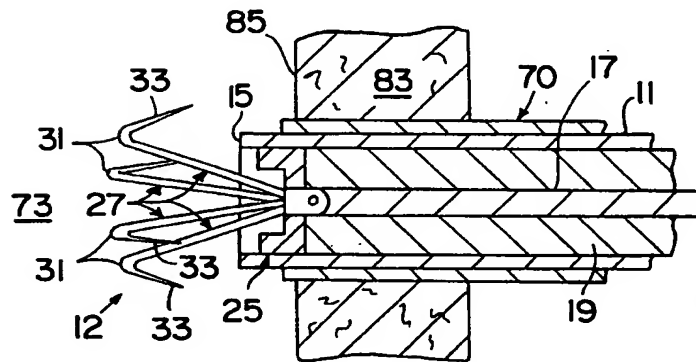


FIG. 7

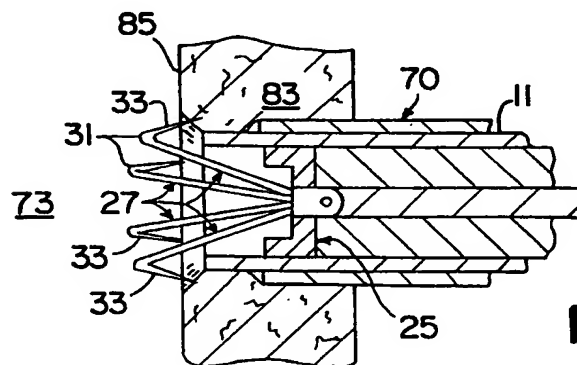


FIG. 8

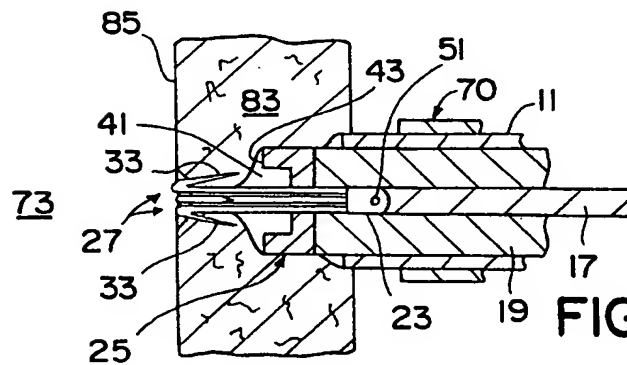


FIG. 9

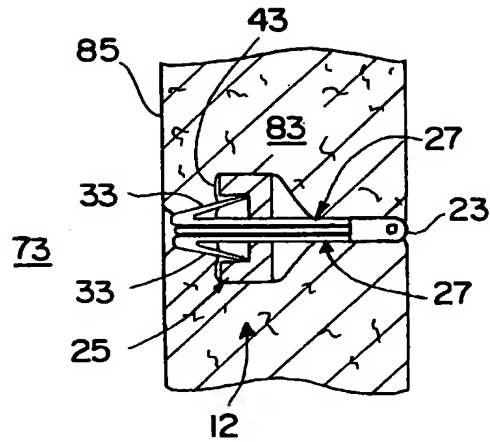


FIG. 10

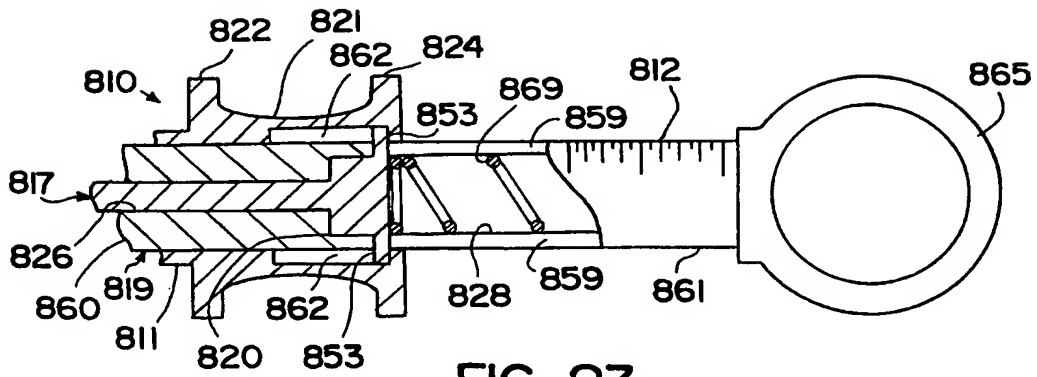


FIG. 23

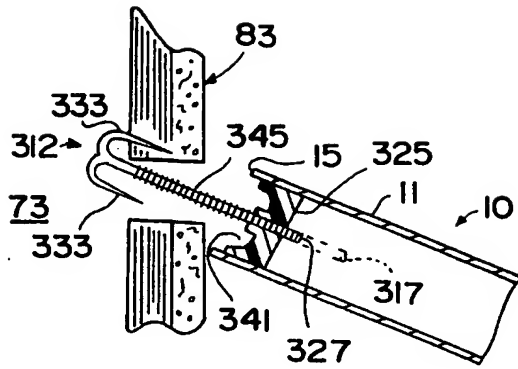


FIG. 14

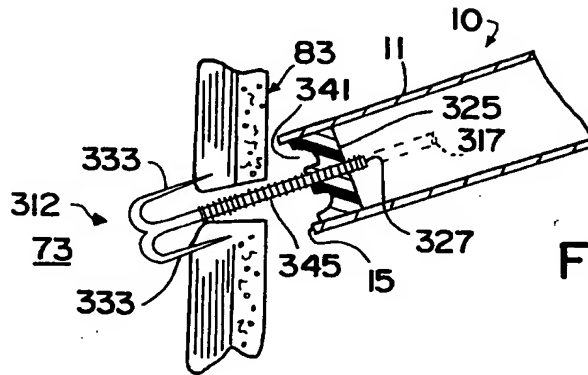


FIG. 15

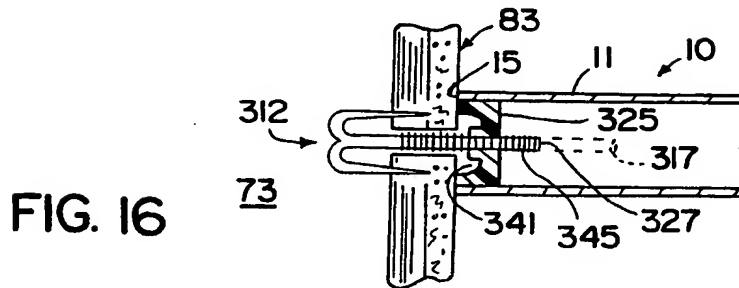


FIG. 16

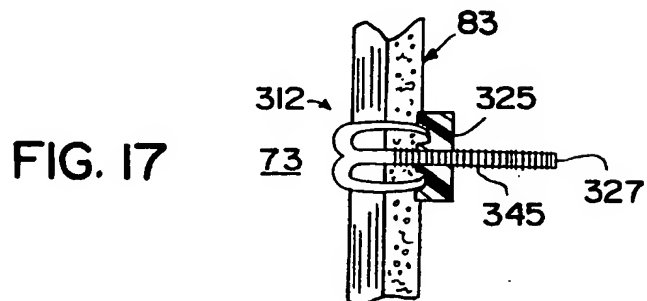
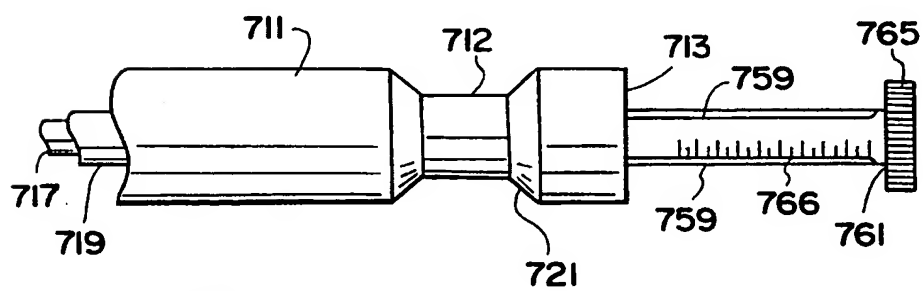
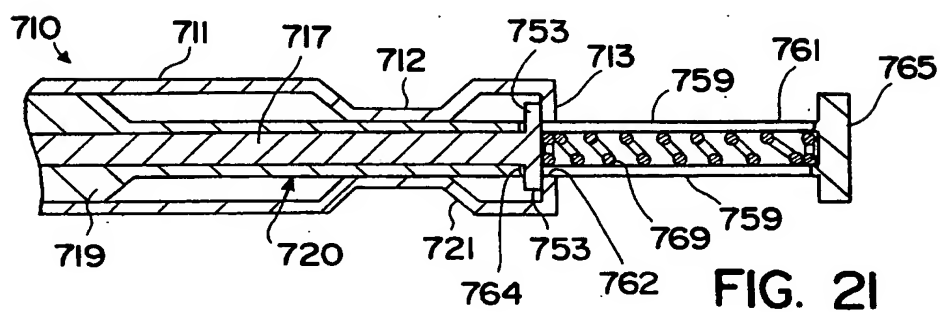
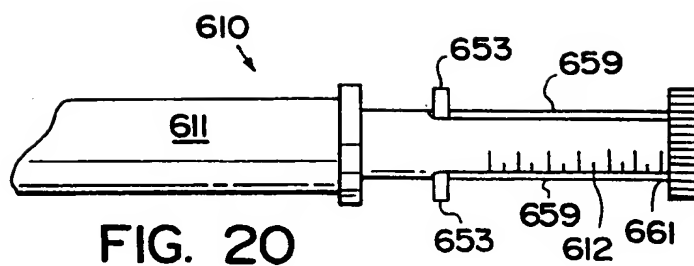


FIG. 17



## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US95/10625**A. CLASSIFICATION OF SUBJECT MATTER**

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**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/139, 151, 213

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 5,104,399 (LAZARUS) 14 April 1992, col. 2, lines 23-68 and col. 3, lines 1-18.	1-39
A	US, A, 5,370,646 (REESE ET AL) 06 December 1994, see abstract	1-39
A	US, A, 5,374,275 (BRADLEY ET AL) 20 December 1994, col. 3, lines 3-60.	1-39



Further documents are listed in the continuation of Box C.



See patent family annex.

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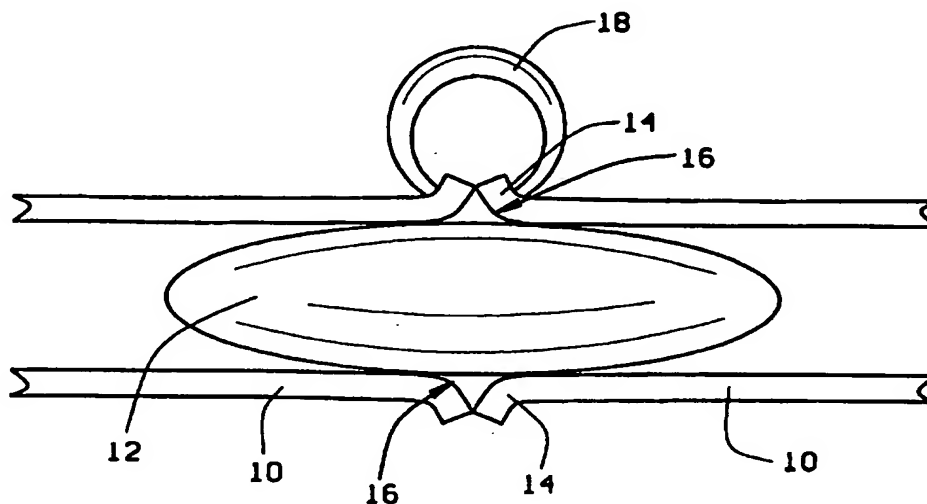
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(54) Title: DEVICE AND METHOD FOR VASCULAR ANASTOMOSIS



(57) Abstract

A temporary stent (12) and method for vascular anastomosis are disclosed. The method comprises placing, in a vessel (10) to be anastomosed, a stent (12) comprising a biocompatible material; applying staples (18) to anastomose the vessel (10); and converting the stent (12) material into a liquid that is miscible with blood by melting with warmed saline or pulsed radiation. Also disclosed is a method and composition for delivery of a drug that prevents thrombus formation and/or intimal hyperplasia at the anastomosis.

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DEVICE AND METHOD FOR VASCULAR ANASTOMOSISBackground of the Invention

## (1) Field of the Invention

This invention generally relates to the field of reconstructive vascular surgery and, more particularly, to a device and method for vascular anastomosis.

## 5 (2) Description of the Related Art

Since the first successful vascular anastomosis was performed at the turn of the century, the search for an easier and faster technique than conventional needle-and-thread suturing has challenged surgeons. Payer was  
10 the first to describe a technique for sutureless vascular anastomosis using a magnesium ring. (Metalles in den Chirurgie. Arch. Klin. Chir. 62:67, 1900). This principle was modified by Nakayama et al. and further modified by Östrup and Berggren into an apparatus for  
15 microvascular anastomosis which is commonly used today. (Nakayama et al., Surgery 52:918-931, 1962; First Scandinavian Seminar on Reconstructive Microsurgery, Gothenburg, Sweden, October 1979, pp. 521-525, 1986. Although this apparatus has a number of advantages, it is  
20 still far from the ideal vascular anastomosis device. The wall of the arteries is usually too thick and rigid to permit the necessary vessel eversion. This problem is even more severe in diseased vessels and limits the use of this device in vascular surgery. Furthermore, the  
25 device is quite cumbersome and the surgical methods required for its use are difficult to master. Nonetheless, for lack of anything better, and because it saves operating time, the device is routinely used today in microvascular free flap surgery to anastomose veins.

30 An alternative to suturing the vessel, is the use of tiny staples or microvascular clips to bring vessel edges together circumferentially. (For example see Kirsch et al, *The American Surgeon* 12:722-727, 1992, which is incorporated herein by reference). Use of these staples  
35 is, however, limited by the problem that in order to achieve accurate placement of the staples, eversion of

the edges of the vessel wall, and the avoidance of a "backwall" bite, an assistant is required to hold the vessel edges up while the staples are inserted. Not only is this inconvenient, such assistance is not always possible such as, for example, in endoscopic procedures.

The use of stents in vascular reconstruction can both facilitate the procedure itself and improve the outcome, particularly in small vessels and in veins. Temporary stents have been used in vascular surgery that are removed prior to complete closure of the anastomosis. These have been reported to improve the ease and rapidity of the anastomosis as well as decrease the danger of injury to the lumen and posterior wall and improve the percent of anastomoses remaining patent. (Wei et al., *British J Plastic Surg* 35:92-95, 1982, which is incorporated herein by reference). Soluble intravascular stents that dissolve and need not be removed have also been reported. Kamiiji et al. used a polyethylene glycol stent that reportedly is washed away by the blood flow and dissolved after restoring blood flow. (*British J Plastic Surg* 42:54-58, 1989, which is incorporated herein by reference). In addition, stents have been reported that, upon completion of the anastomosis, can be melted or dissolved by warm isotonic saline and subsequently washed away in the blood on restoring blood flow (Cong et al, *Microsurgery* 12:67-71, 1991; Moskovitz et al, *Annals Plastic Surgery* 32:612-618, 1994, which are incorporated herein by reference). These groups used stents composed of a mixture of mono-, di-, and triglycerides that melt at temperatures near body temperature. Because the glycerides are normal elements in the blood stream, the stent was considered biocompatible.

Particular advantages reported on use of the stent with suturing of the anastomosis were an improvement in the accuracy and speed of the procedure, the minimizing of minor trauma, the avoidance of suture errors such as a

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partial bite of the opposite wall, the achieving of a better coaptation of cut edges, the avoidance of narrowing at the anastomosis sites, the achieving of even distribution between stitches, and the preventing of vasospasm (Cong et al., 1991). Use of the stent with fibrin glue was reported to have the disadvantage of producing aneurysms. Although one group used the stent in combination with sutures, neither used the stents in combination with staples. Use of staples would be expected to reduce the likelihood of aneurysm formation compared to the use of fibrin glue because of the staples firmly holding the media in close enough apposition to allow proper healing over time. Furthermore, staples would be expected to decrease the time required for the procedure compared to use of suturing with the stent.

The use of a stent in combination with staples has not been appreciated as an advantage over the staples alone in open field microvascular anastomosis inasmuch as it has been reported that a stent is not necessary with microclip anastomosis (Kirsch et al, 1992). In the non-vascular anastomosis of vasovasostomy, an absorbable stent was used in combination with microvascular clips. (Gaskill et al, *Urology* 40:191-194, 1992, which is incorporated herein by reference). The stent was hollow and composed of polyglycolic acid. Furthermore, the stent was not immediately absorbable as would be required for such a temporary stent in a vascular anastomosis. This group reported that the combination of an absorbable stent with microclips allowed a shorter time for completion of the procedure (7.6 v. 8.5 minutes) and required less care. Nevertheless, it was indicated that there was no advantage to using the stent because of a high percentage of granulomas following its use apparently resulting from the need for more clips to seal the anastomosis or from obstruction of the stent. The requirement for more clips may indicate a failure of the

stent to fit snugly into the vessel. Furthermore, obstruction from the stent is likely to have been a result of the stent dissolving over a relatively long period of time. Moreover, this reference did not apply  
5 the technique using the slowly absorbable stent along with stapling to vascular anastomosis.

Thus, in performing a vascular anastomosis, it would be desirable to have an improved method that is easy and rapid and that does not require an expert  
10 surgical assistant and that also produces an eversion of the vessel edges and avoids a "backwall" bite.

One of the problems that can be associated with vascular anastomosis is the formation of thrombus at the anastomosis. The thrombus results from a gradual  
15 accumulation of platelets at the anastomosis and the formation of fibrin. The thrombus thus formed could eventually occlude the vessel. It would be desirable, therefore, to provide some means to diminish the likelihood of formation of a thrombus at the anastomosis  
20 site.

#### Summary of the Invention

In view of the limitations with existing methods, Applicant has succeeded in devising an improved device and method for vascular anastomosis. The method  
25 comprises the steps of placing, in vessels to be anastomosed, a stent comprising a biocompatible material; applying staples to anastomose the vessels; and converting the stent material into a liquid that is miscible with blood by melting with warmed saline, pulsed  
30 radiation or otherwise.

In accordance with the present invention, it has been discovered that utilization of a temporary stent for vascular anastomosis holds the vessel edges approximated together and stabilizes them while functioning as an  
35 anvil against which the stapler can safely apply pressure without fear of catching the posterior wall. The stent

is also designed in a shape that tends to cause eversion of the vessel edges and facilitates approximation of intima to intima. The stent is made of a biocompatible material which is rapidly melted upon applying heat,  
5 pulsed radiation such as laser energy or U.V. light, etc. and completely miscible with blood on flushing out the anastomosis by restoring blood flow.

Surprisingly, the method could be performed by a novice in substantially less time than the conventional  
10 suture anastomosis could be performed by an expert. Furthermore, anastomoses performed using the stent with staples showed excellent approximation of the intimal edges and no significant anastomotic stenosis.

Thus the present invention provides the vascular  
15 surgeon with new and improved procedure for performing vascular anastomosis that is faster and easier to perform and that provides an excellent outcome. This new method is particularly applicable to endoscopic procedures where the otherwise extremely difficult sutured anastomosis can  
20 now be replaced with an easier, faster and safer anastomosis using staples available and well known in the art combined with a stent. In addition, the new method herein provides the vascular surgeon with an approach that can be used for end-to-side anastomoses by using a  
25 T-shaped or Y-shaped stent.

Furthermore, the stent could also function as a drug delivery device. Thus, the present invention is also directed to a stent for use in vascular anastomosis comprising a substance that prevents thrombus formation  
30 as well as to a method for preventing thrombus formation at a site of vascular anastomosis in an individual comprising administering to the individual a substance that prevents thrombus formation. The incorporation of the drug into the stent would allow a continuous release  
35 of the drug once placed in the lumen during the anastomosis procedure. Then upon melting and dissolving

or emulsifying the anastomosis, the drug within the stent would be immediately released.

Among the several advantages found to be achieved by the present invention, therefore, may be noted the provision of a method of vascular anastomosis for improved accuracy and speed compared to use of the stent alone or with suturing or compared to stapling alone; the provision of a method of vascular anastomosis that avoids the danger of injury to the lumen or posterior wall from the staples; and the provision of a method and device for vascular anastomosis that utilize a stent to deliver a bioactive drug to prevent undesirable complications such as the formation of thrombus or intimal hyperplasia.

While the principal advantages and features of the present invention have been described above, a more complete and thorough understanding of the invention may be attained by referring to the drawings and description of the preferred embodiment which follow.

#### Brief Description of the Drawings

The drawing illustrates use of the stent and staples of the present invention in vascular anastomosis.

#### Description of Preferred Embodiments

As shown in the figure, a stent 12 is placed in the lumen of vessel 10. The stent has an oval shape in which the longitudinal axis length is greater than the transverse axis length. Thus, there is a lengthwise tapering from the center to the end. This design effectively causes an eversion of the edges 14 of the vessel 10 to facilitate approximation of the intima 16 of each of the two edges. This is explained in greater detail, infra. Staple 18 pinches together the edges 14 of the vessel 10 bringing together the intima 16.

The stent material as placed in the lumen of the vessels is solid and must be of sufficient strength to be able to act as an anvil against which the staples are applied. By applying the staples against the stent, the

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likelihood of penetration of the staple into the lumen and injury to the inner lining of the vessel wall is diminished. Furthermore, the stent prevents a deeper penetration to the posterior wall on opposite side of the vessel lumen thus precluding backwall injury.

The stent can be made up of any solid material, which upon completion of the anastomosis, can be rapidly melted or dissolved and that is readily miscible with blood upon restoring flow through the anastomosis.

The melting or dissolving of the stent can be accomplished by any suitable means, for example by irrigating the operative field with warmed saline. Alternatively, the stent material can be melted by pulsed radiation such as with a laser, U.V. light, or by any other means that can convert the solid stent material into a liquid.

Examples of stent materials useful in the present invention are mixtures of mono-, di- and triglycerides, polyglycolic acids and polyethylene glycol. The stent materials are readily miscible with blood either by virtue of being water soluble or by being readily able to form an emulsion or dispersion with blood. Polyethylene glycol 1500, which is water soluble and melts between 44°C and 48°C is an example of stent material useful in the present invention. A preferred stent material is a mixture of mono-, di- and triglycerides that consists mostly of triglycerides with diglycerides present in a concentration of 15% or less and monoglycerides present in a concentration of 1% or less. This mixture is sold under the trademark WITEPSOL® and the manufacturer's identification H 37 (Hüls, AG, Witten, Germany; Hüls America, Piscataway, N.J.). WITEPSOL® H 37 comprises glycerol esters of vegetable saturated fatty acids, mainly lauric acid prepared from coconut and palm kernel oils. (See Hüls WITEPSOL® product bulletin which is incorporated by reference). It is a solid with a melting

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point between 36°C and 38°C. Saline warmed to approximately 45°C rapidly melts this material.

The stent material must also be biocompatible. In addition, the liquid stent material by virtue of being  
5 readily dissolved, emulsified or dispersed in the blood, produces no deleterious effect upon restoring blood flow and flushing from the anastomosis.

The stent materials disclosed above are exemplary only and the skilled artisan will appreciate that stents  
10 within the scope of this invention can be comprised of any suitable material that satisfies the criteria set forth above.

Methods for preparation of stents are well known in the literature. (See for example Cong et al.,  
15 *Microsurgery* 12:67-71, 1991; Moskovitz et al, *Ann Plastic Surg* 32:612-618, 1994; Kamiji et al., *Brit J Plastic Surg* 42:54-58, 1989, which are incorporated herein by reference). Stents can be fabricated in virtually any desired size, although the shape and size depicted in the  
20 preferred embodiment has been found to be particularly helpful in everting the vessel sidewalls.

The stent for use in anastomosis of a particular vessel is selected so that it will fit snugly inside the lumen of that vessel. As shown in the figure, as the  
25 stent is inserted into the vessel, its sidewalls eventually contact the stent and are angled obliquely, or radially outward. After insertion into both ends, the vessel sidewalls contact each other obliquely and are readily everted upon further advance.

30 Staple, 18, can be any of a number well known in the art and devices for applying staples are also well known in the art. (See for example Kirsch et al, *Am Surgeon* 58:722-727, 1992; Tredway et al., *Fertil Steril* 62:624-629, 1994, which are incorporated herein by  
35 reference). The staples can be made of any biocompatible material such as, for example, titanium. The size of the

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stables is selected according to the wall thickness of the vessel being anastomosed and the jaw opening can be in the range of from approximately 0.3 mm to approximately 2 mm. The present invention is applicable  
5 to anastomosis of vessels of virtually any size including vessels as large as the abdominal aorta as well as vessels as small as 1 mm in diameter and smaller. The methods and compositions herein are also applicable to both arteries and veins.

10 Vascular anastomosis performed by the present improved procedure is faster and easier to perform while providing an excellent outcome. Because of this, the present improved method facilitates the performance of otherwise extremely difficult anastomosis procedures.  
15 For example, the present invention provides a practical method for endoscopic vascular surgery. The method can also be used with L-shaped or T-shaped stents for use in end-to-side anastomosis. This provides a practical method for coronary artery bypass grafts where an end-to-  
20 side anastomosis is desired.

The stent can also act as a means to locally deliver bioactive agents that have beneficial effects upon the anastomosis. The incorporation of a drug into the stent would allow local release of the drug during  
25 the anastomosis procedure and particularly upon the melting and dissolution or emulsion of the stent inside the anastomosis. This provides a very practical method for direct delivery of the drug to the anastomosis. One example of such a bioactive agent that can be  
30 incorporated into the stent for delivery to the anastomosis is recombinant Tissue Factor Pathway Inhibitor (TFPI). TFPI reduces the buildup of thrombus at the anastomosis, improves the patency rate of the vascular anastomosis (Khoury et al., U.S. Patent No.  
35 5,276,015 which is incorporated by reference). The inventor also believes that TFPI can reduce the amount of

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intimal hyperplasia which develops at vascular anastomoses. The incorporation of such an agent into the stent material would represent an ideal method of local drug delivery.

5       The above disclosure generally describes the present invention. A more complete understanding can be obtained by reference to the following specific examples which are provided herein for purposes of illustration only and are not intended to be limiting unless otherwise  
10 specified.

#### EXAMPLE 1

The preparation of stents is illustrated in the method used for making the 10 mm stents.

15       Stents having a diameter of 10 mm were fabricated from 1 g WITEPSOL® H 37. WITEPSOL® H 37 is a solid with a melting point between 36 and 38°C. It is widely used in pharmaceuticals for drug delivery. The pastilles were carefully warmed up to 45°C in a water bath and the  
20 molds were in a generally oval shape providing a tapering of the two ends of the stent. The material was allowed to cool down and harden at room temperature. The stents were removed from the mold, gas sterilized and stored at -20°C. On the day of surgery, the stents were kept in an  
25 ice-saline bath until they are inserted into the vessel ends.

#### Example 2

This example illustrates the method of anastomosis of large and small vessel using the abdominal aorta and  
30 small arteries in pigs and rabbits.

In 5 American farm pigs (30kg), a median laparotomy was performed and the abdominal aorta was dissected transperitonially and divided between vascular clamps. A 10 mm stent of WITEPSOL® H 37 (1 g) was  
35 inserted into the divided vessel stumps. The shape of the stent was such that it caused a slight eversion of

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the edges and facilitated intimal approximation. In the first experiment the anastomosis was performed by applying approximately 20 staples with Endopath EAS. In the following 4 experiments, the anastomoses were performed with Endopath EMS and a smaller number of staples was required. The experiments were performed by the operator alone, without an assistant holding the vessel edges. At the completion of the anastomoses, the operative field was irrigated with warm saline (45°C) until the stent completely dissolved (10-15 seconds). The clamps were released and the anastomoses were observed for 60 minutes. The animals were sacrificed with an overdose of barbiturates and a lead oxide angiography was performed. The abdominal aorta, including the anastomosis was then resected and submitted for histological evaluation.

Abdominal aortas (3mm), carotid arteries (2mm), and central ear arteries (1mm), were dissected in New Zealand white rabbits and divided between vascular clamps. In 5 animals a conventional sutured anastomosis was performed by a single experienced microsurgeon without an assistant. In 5 animals a stented and stapled anastomosis was performed by a single novice microsurgeon without an assistant and without prior experience with the use of the stapler. To perform the stented and stapled anastomosis, the vessels were approximated over the stent and held together by applying 8 microstaples around the circumference. The stents were made of an inert triglyceride compound (WITEPSOL® H 37), which melts at body temperature. They were designed such that they fitted snugly inside the lumen and caused an eversion of the edges to facilitate intimal approximation. At the completion of the anastomoses, the vessels were irrigated with warm saline (45°C) until the stents completely dissolved (10-15 seconds), and the clamps were then released. The time taken to complete the anastomosis

(clamp on/clamp off), and one day and one week patency were recorded. Angiograms were performed and the vessels were perfusion fixed at one week to determine the presence of anastomotic stenosis. Using T-shaped stents, end-to-side anastomoses were performed and compared with similar sutured anastomoses.

All anastomoses were patent at one day and one week. The average time taken by the novice to perform the stapled anastomosis alone was 2.5 minutes. In contrast, it took the experienced vascular surgeon 9 minutes to perform the sutured anastomoses ( $p < 0.01$ ). All the stapled anastomoses had excellent approximation of the intimal edges without significant anastomotic stenosis. There was no observable side effect from the stent material.

These experiments demonstrate the stapled vascular anastomosis using a soluble intraluminal stent that acts as an anvil. The presence of a stent made the stapling very practical and simple. The stent is made up of a solid material which can dissolve on command at the completion of the anastomosis. There were no observed deleterious effects from the bolus of lipid infusion which resulted when the lipid stent dissolved, although other potential materials could be found which can become soluble by pulsed radiation or other physical means.

In view of the above, it will be seen that the several objects of the invention are achieved and other advantageous results attained.

As various changes could be made in the above constructions without departing from the scope of the invention, it is intended that all matter contained in the above description shall be interpreted as illustrative and not in a limiting sense.

What is Claimed is:

1. A method for vascular anastomosis in a subject comprising the steps of:

- (a) placing, in a vessel to be anastomosed, a stent comprising a biocompatible material;  
5 (b) applying staples to anastomose the vessel; and  
(c) converting the stent material into a liquid that is miscible with blood.

2. The method according to claim 1 wherein the stent material melts upon applying heat and the step of converting the material to a liquid includes the step of applying heat.

3. The method according to claim 2 wherein the step of applying heat includes the step of irrigating the operative field with warmed saline.

4. The method according to claim 3 wherein the stent comprises a material selected from the group consisting of a mixture of monoglycerides, diglycerides and triglycerides; a polyglycolic acid; a polyethylene  
5 glycol; and mixtures thereof.

5. The method according to claim 4 wherein the stent material comprises WITEPSOL® H 37.

6. The method according to claim 1 wherein the stent material melts on applying pulsed radiation and the step of converting the material to a liquid includes the step of applying pulsed radiation.

7. The method according to claim 6 wherein the stent comprises a material selected from the group consisting of a mixture of monoglycerides, diglycerides and triglycerides; a polyglycolic acid; a polyethylene  
5 glycol; and mixtures thereof.

8. The method according to claim 1 wherein the anastomosis is an end-to-end anastomosis and the stent has a center and two opposite ends, and a lengthwise tapering from the center to each end.

9. The method according to claim 1 wherein the anastomosis is an end-to-side anastomosis and the stent is in an L-shape, a T-shape or a Y-shape.

10. The method according to claim 1 wherein the stent contains a substance that prevents thrombus formation and/or intimal hyperplasia.

11. The method according to claim 10 wherein the substance that prevents thrombus formation and/or intimal hyperplasia comprises Tissue Factor Pathway Inhibitor (TFPI).

12. A temporary stent for use in vascular anastomosis comprising a biocompatible material that can be converted to a liquid that is miscible with blood and a substance that prevents thrombus formation and/or  
5 intimal hyperplasia.

13. The stent according to claim 12 wherein the stent is comprised of a material which will convert to liquid upon application of heat or pulsed radiation.

14. The stent according to claim 13 wherein the substance that prevents thrombus formation and/or intimal hyperplasia is released from the stent material upon converting to the liquid.

15. The stent according to claim 12 wherein the substance that prevents thrombus formation and/or intimal hyperplasia comprises TFPI.

16. A method for preventing thrombus formation and/or intimal hyperplasia at a site of vascular anastomosis in an individual comprising administering to the individual a substance that prevents thrombus  
5 formation and/or intimal hyperplasia.

17. The method of claim 16 wherein the substance that prevents thrombus formation and/or intimal hyperplasia is administered at the site of vascular anastomosis.

18. The method according to claim 17 wherein the substance that prevents thrombus formation and/or intimal

hyperplasia is released from a stent at the site of vascular anastomosis.

19. The method according to claim 18 wherein the substance that prevents thrombus formation and/or intimal hyperplasia is TFPI.

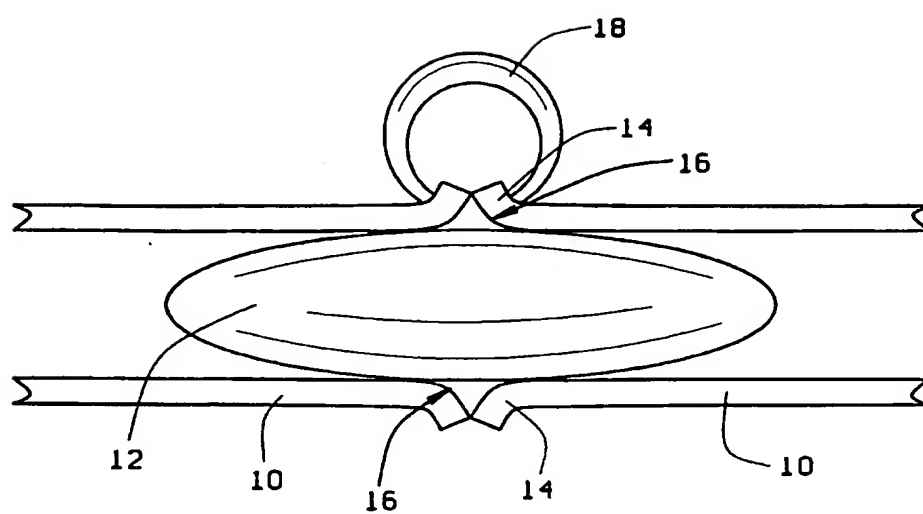
20. The method according to Claim 1 wherein the step of placing the stent includes the step of everting the vessel sidewalls as the stent is advanced into the vessel.

21. The method according to Claim 20 wherein the stent has a portion with a cross-sectional area sized to fit snugly within said vessel.

22. The method according to Claim 21 wherein the stent has a center and two opposite ends, and a lengthwise tapering from the center to each end, said center comprising said snugly fitting portion.

23. A temporary stent for use in vascular anastomosis comprising a biocompatible material that can be converted to a liquid that is miscible with blood, said stent having a pair of opposing tapered surfaces  
5 which meet at a center, said center having a cross-sectional area sized to fit snugly within said vessel so that said vessel sidewalls are everted as said stent is inserted in said vessel.

**BAD ORIGINAL**



## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US96/05815

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/06

US CL :623/1

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/898; 606/154, 194; 623/1, 6, 12, 15

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y --- A	THE AMERICAN SURGEON, December 1991, Vol. 58, No. 12, (KIRSCH ET AL.) A New Method for Microvascular Anastomosis: Report of Experimental and Clinical Research, pages 722-727.	1-11, 20-23 ----- 12-19
Y --- A	US, A, 5,141,516 (DETWEILER) 25 August 1992, see column 1 lines 8-12, column 2 lines 5-10, column 4 lines 8-11, column 7 lines 20-23, column 5 lines 1-35, and Fig. 2.	1-11, 20-23 ----- 12-19
Y	US, A, 4,770,176 (MCGREEVY ET AL.) 13 September 1988, see column 4 lines 41-54.	2-7, 12-19

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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*O* document referring to an oral disclosure, use, exhibition or other means	
*P* document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

26 JUNE 1996

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International application No.  
PCT/US96/05815

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
Y --- A	Wiley-Liss, Inc., 1991, (CONG ET AL.) EXPERIMENTAL STUDY ON MICROVASCULAR ANASTOMOSIS USING A DISSOLVABLE STENT SUPPORT IN THE LUMEN, Dept. of Orthopaedic Surgery, Air Force Hospital, No. 1, Gongnongyuan Street, Chengau, Sichuan, People's Republic of China 610061, pp.67-71.	3-5 ----- 12-19
Y --- A	Annals of Plastic Surgery, Volume 21/Number 6/June 1994, (MOSKOVITZ ET AL.) Microvascular Anastomoses Utilizing New Intravascular Stents, 180 Clinton St., Brooklyn, NY 11201, pp.612-618.	3-5 ----- 12- 19
Y --- A	British Journal of Plastic Surgery (1989), The Trustees of British Association of Plastic Surgeons, (T. KAMIJI ET AL.) Microvascular anastomosis using polyethylene glycol 4000 and fibrin glue, pp.54-58.	3-5 ----- 12-19
Y --- P A	US, A, 5,464,450 (BUSCEMI ET AL.) 07 November 1995, see column 5 lines 10-20.	4, 5, 7, 9-11 ----- 12-19
Y	US, A, 5,276,015 (KHOURI ET AL.) 04 January 1994, see column 2 lines 42-49.	11
Y	US, A, 3,908,662 (RAZGULOV ET AL.) 30 September 1975, see column 5 lines 23-27, and column 10 lines 32-44.	20-23

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/US96/01890 (22) International Filing Date: 13 February 1996 (13.02.96) (30) Priority Data: 08/394,333 24 February 1995 (24.02.95) US (71) Applicant: HEARTPORT, INC. [US/US]; 200 Chesapeake Drive, Redwood City, CA 94063 (US). (72) Inventors: GIFFORD, Hanson, S., III; 3180 Woodside Road, Woodside, CA 94062 (US). BOLDUC, Lee, R.; 761 1/2 Palo Alto Avenue, Mountain View, CA 94041 (US). STEIN, Jeffrey, A.; 11 Pinehill Road, Woodbridge, CT 06525 (US). DICESARE, Paul, C.; 10 Jarvis Street, Norwalk, CT 06851 (US). COSTA, Peter, F.; 80 Johnson Avenue, Winthrop, MA 02152 (US). HOLMES, William, A.; 7 Bradlee Road, Marblehead, MA 01945 (US). (74) Agents: HESLIN, James, M. et al.; Townsend and Townsend and Crew, Steuart Street Tower, 20th floor, One Market Plaza, San Francisco, CA 94105 (US).</p>		<p>(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>
<p>(54) Title: DEVICES AND METHODS FOR PERFORMING A VASCULAR ANASTOMOSIS</p> <div data-bbox="397 1102 1201 1585"></div> <p>(57) Abstract</p> <p>A system for performing an end-to-side vascular anastomosis, including an anastomosis device, an application instrument and methods for performing a vascular anastomosis. The system is applicable for performing an anastomosis between a vascular graft and the ascending aorta in coronary artery bypass surgery, particularly in port-access CABG surgery. A first aspect of the invention includes a vascular anastomosis staple. A first configuration has two parts: an anchor member (101), forming the attachment with the target vessel wall and a coupling member (102) forming the attachment with the bypass graft vessel. The anastomosis is completed by inserting the coupling member (102), with the graft vessel attached, into the anchor member (101). A second configuration combines the functions of the anchor member and the coupling member into a one-piece anastomosis staple. A second aspect of the invention includes an anastomotic fitting, having an inner flange over which the graft vessel is everted and an outer flange which contacts the exterior surface of the target vessel.</p>		

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10           The present invention relates generally to devices and methods for surgically performing an end-to-side anastomosis of hollow organs. More particularly, it relates to vascular anastomosis devices for joining the end of a graft vessel, such as a coronary bypass graft, to the side wall of a target vessel, such as the aorta or a coronary artery.

Anastomosis is the surgical joining of biological tissues, especially the joining of tubular organs to create an intercommunication between them. Vascular surgery often involves creating an anastomosis between blood vessels or between a blood vessel and a vascular graft to create or restore a blood flow path to essential tissues. Coronary artery bypass graft surgery (CABG) is a surgical procedure to restore blood flow to ischemic heart muscle whose blood supply has been compromised by occlusion or stenosis of one or more of the coronary arteries. One method for performing CABG surgery involves harvesting a saphenous vein or other venous or arterial conduit from elsewhere in the body, or using an artificial conduit, such as one made of Dacron or Goretex tubing, and connecting this conduit as a bypass graft from a viable artery, such as the aorta, to the coronary artery downstream of the blockage or narrowing. A graft with both the proximal and distal ends of the graft detached is known as a "free graft". A second method involves rerouting a less essential artery, such as the internal mammary artery, from its native location so that it may be connected to the coronary artery downstream of the blockage. The proximal end of the graft vessel remains attached in its native position.

This type of graft is known as a "pedicled graft". In the first case, the bypass graft must be attached to the native arteries by an end-to-side anastomosis at both the proximal and distal ends of the graft. In the second technique at least one end-to-side anastomosis must be made at the distal end of the artery used for the bypass. In the description below we will refer to the anastomoses on a free graft as the proximal anastomosis and the distal anastomosis. A proximal anastomosis is an anastomosis on the end of the graft vessel connected to a source of blood (e.g. the aorta) and a distal anastomosis is an anastomosis on the end of the graft vessel connected to the destination of the blood flowing through it (e.g. a coronary artery). The anastomoses will also sometimes be called the first anastomosis or second anastomosis, which refers to the order in which the anastomoses are performed regardless of whether the anastomosis is on the proximal or distal end of the graft.

At present, essentially all vascular anastomoses are performed by conventional hand suturing. Suturing the anastomoses is a time-consuming and difficult task, requiring much skill and practice on the part of the surgeon. It is important that each anastomosis provide a smooth, open flow path for the blood and that the attachment be completely free of leaks. A completely leak-free seal is not always achieved on the very first try. Consequently, there is a frequent need for resuturing of the anastomosis to close any leaks that are detected.

The time consuming nature of hand sutured anastomoses is of special concern in CABG surgery for several reasons. Firstly, the patient is required to be supported on cardiopulmonary bypass (CPB) for most of the surgical procedure, the heart must be isolated from the systemic circulation (i.e. "cross-clamped"), and the heart must usually be stopped, typically by infusion of cold cardioplegia solution, so that the anastomosis site on the heart is still and blood-free during the suturing of the anastomosis. CPB, circulatory isolation and cardiac arrest are inherently very traumatic, and it has been found that the frequency of certain

post-surgical complications varies directly with the duration for which the heart is under cardioplegic arrest (frequently referred to as the "crossclamp time"). Secondly, because of the high cost of cardiac operating room time, any prolongation of the surgical procedure can significantly increase the cost of the bypass operation to the hospital and to the patient. Thus, it is desirable to reduce the duration of the crossclamp time and of the entire surgery by expediting the anastomosis procedure without reducing the quality or effectiveness of the anastomoses.

The already high degree of manual skill required for conventional manually sutured anastomoses is even more elevated for closed-chest or port-access thoracoscopic bypass surgery, a newly developed surgical procedure designed to reduce the morbidity of CABG surgery as compared to the standard open-chest CABG procedure. This procedure is more fully described in commonly-assigned, co-pending patent applications 08/023,778, filed February 22, 1993, and 08/281,981, filed July 28, 1994, the complete disclosures of which are hereby incorporated by reference. In the closed-chest procedure, surgical access to the heart is made through narrow access ports made in the intercostal spaces of the patient's chest, and the procedure is performed under thoracoscopic observation. Because the patient's chest is not opened, the suturing of the anastomoses must be performed at some distance, using elongated instruments positioned through the access ports for approximating the tissues and for holding and manipulating the needles and sutures used to make the anastomoses. This requires even greater manual skill than the already difficult procedure of suturing anastomoses during open-chest CABG surgery.

In order to reduce the difficulty of creating the vascular anastomoses during either open or closed-chest CABG surgery, it would be desirable to provide a rapid means for making a reliable end-to-side anastomosis between a bypass graft or artery and the aorta or the native vessels of the heart. A first approach to expediting and improving anastomosis procedures has been through stapling technology.

Stapling technology has been successfully employed in many different areas of surgery for making tissue attachments faster and more reliably. The greatest progress in stapling technology has been in the area of gastrointestinal surgery. Various surgical stapling instruments have been developed for end-to-end, side-to-side, and end-to-side anastomoses of hollow or tubular organs, such as the bowel. These instruments, unfortunately, are not easily adaptable for use in creating vascular anastomoses. This is partially due to the difficulty in miniaturizing the instruments to make them suitable for smaller organs such as blood vessels. Possibly even more important is the necessity of providing a smooth, open flow path for the blood. Known gastrointestinal stapling instruments for end-to-side or end-to-end anastomosis of tubular organs are designed to create an inverted anastomosis, that is, one where the tissue folds inward into the lumen of the organ that is being attached. This is acceptable in gastrointestinal surgery, where it is most important to approximate the outer layers of the intestinal tract (the serosa). This is the tissue which grows together to form a strong, permanent connection. However, in vascular surgery this geometry is unacceptable for several reasons. Firstly, the inverted vessel walls would cause a disruption in the blood flow. This could cause decreased flow and ischemia downstream of the disruption, or, worse yet, the flow disruption or eddies created could become a locus for thrombosis which could shed emboli or occlude the vessel at the anastomosis site. Secondly, unlike the intestinal tract, the outer surfaces of the blood vessels (the adventitia) will not grow together when approximated. The sutures, staples, or other joining device may therefore be needed permanently to maintain the structural integrity of the vascular anastomosis. Thirdly, to establish a permanent, nonthrombogenic vessel, the innermost layer (the endothelium) should grow together for a continuous, uninterrupted lining of the entire vessel. Thus, it would be preferable to have a stapling instrument that would create vascular anastomoses that are everted, that is

folded outward, or which create direct edge-to-edge coaptation without inversion.

At least one stapling instrument has been applied to performing vascular anastomoses during CABG surgery. This device, first adapted for use in CABG surgery by Dr. Vasilii I. Kolesov and later refined by Dr. Evgenii V. Kolesov (U.S. patent 4,350,160), was used to create an end-to-end anastomosis between the internal mammary artery (IMA) or a vein graft and one of the coronary arteries, primarily the left anterior descending coronary artery (LAD). Because the device could only perform end-to-end anastomoses, the coronary artery first had to be severed and dissected from the surrounding myocardium, and the exposed end everted for attachment. This technique limited the indications of the device to cases where the coronary artery was totally occluded, and therefore there was no loss of blood flow by completely severing the coronary artery downstream of the blockage to make the anastomosis. Consequently, this device is not applicable where the coronary artery is only partially occluded and is not at all applicable to making the proximal side-to-end anastomosis between a bypass graft and the aorta.

One attempt to provide a vascular stapling device for end-to-side vascular anastomoses is described in U.S. patent 5,234,447, granted to Kaster et al. for a Side-to-end Vascular Anastomotic Staple Apparatus. Kaster et al. provide a ring-shaped staple with staple legs extending from the proximal and distal ends of the ring to join two blood vessels together in an end-to-side anastomosis. However, this device falls short of fulfilling the desired objectives of the present invention. Specifically, Kaster does not provide a complete system for quickly and automatically performing an anastomosis. The method of applying the anastomosis staple disclosed by Kaster involves a great deal of manual manipulation of the staple, using hand operated tools to individually deform the distal tines of the staple after the graft has been attached and before it is inserted into the opening made in the aortic wall. One of the more difficult maneuvers in applying the Kaster staple involves carefully

everting the graft vessel over the sharpened ends of the staple legs, then piercing the everted edge of the vessel with the staple legs. Experimental attempts to apply this technique have proven to be very problematic because of difficulty in manipulating the graft vessel and the potential for damage to the graft vessel wall. For speed, reliability and convenience, it is preferable to avoid the need for complex maneuvers while performing the anastomosis. Further bending operations must then be performed on the staple legs. Once the distal tines of the staple have been deformed, it may be difficult to insert the staple through the aortotomy opening. Another disadvantage of the Kaster device is that the distal tines of the staple pierce the wall of the graft vessel at the point where it is everted over the staple. Piercing the wall of the graft vessel potentially invites leaking of the anastomosis and may compromise the structural integrity of the graft vessel wall, serving as a locus for a dissection or even a tear which could lead to catastrophic failure. Because the Kaster staple legs only apply pressure to the anastomosis at selected points, there is a potential for leaks between the staple legs. The distal tines of the staple are also exposed to the blood flow path at the anastomotic site where it is most critical to avoid the potential for thrombosis. There is also the potential that exposure of the medial layers of the graft vessel where the staple pierces the wall could be a site for the onset of intimal hyperplasia, which would compromise the long-term patency of the graft. Because of these potential drawbacks, it is desirable to make the attachment to the graft vessel as atraumatic to the vessel wall as possible and to eliminate as much as possible the exposure of any foreign materials or any vessel layers other than a smooth uninterrupted intimal layer within the anastomosis site or within the graft vessel lumen.

A second approach to expediting and improving anastomosis procedures is through the use of anastomotic fittings for joining blood vessels together. One attempt to provide a vascular anastomotic fitting device for end-to-side vascular anastomoses is described in U.S. patent 4,366,819,

granted to Kaster for an Anastomotic Fitting. This device is a four-part anastomotic fitting having a tubular member over which the graft vessel is everted, a ring flange which engages the aortic wall from within the aortic lumen, and a fixation ring and a locking ring which engage the exterior of the aortic wall. Another similar Anastomotic Fitting is described in U.S. patent 4,368,736, also granted to Kaster. This device is a tubular fitting with a flanged distal end that fastens to the aortic wall with an attachment ring, and a proximal end with a graft fixation collar for attaching to the graft vessel. These devices have a number of drawbacks that the present invention seeks to overcome. Firstly, the anastomotic fittings described expose the foreign material of the anastomotic device to the blood flow path within the arteries. This is undesirable because foreign materials within the blood flow path can have a tendency to cause hemolysis, platelet deposition and thrombosis. Immune responses to foreign material, such as rejection of the foreign material or auto-immune responses triggered by the presence of foreign material, tend to be stronger when the material is exposed to the bloodstream. As such, it is preferable that as much as possible of the interior surfaces of an anastomotic fitting that will be exposed to the blood flow path be covered with vascular tissue, either from the target vessel or from the graft vessel, so that a smooth, continuous, hemocompatible endothelial layer will be presented to the bloodstream. The anastomotic fitting described by Kaster in the '819 patent also has the potential drawback that the spikes that hold the graft vessel onto the anastomotic fitting are very close to the blood flow path, potentially causing trauma to the blood vessel that could lead to leaks in the anastomosis or compromise of the mechanical integrity of the vessels. Consequently, it is desirable to provide an anastomosis fitting that is as atraumatic to the graft vessel as possible. Any sharp features such as attachment spikes should be placed as far away from the blood flow path and the anastomosis site as possible so that there is no compromise of the anastomosis seal or the structural integrity of the vessels.

Another device, the 3M-Unilink device for end-to-end anastomosis (U.S. patent numbers 4,624,257; 4,917,090; 4,917,091) is designed for use in microsurgery, such as for reattaching vessels severed in accidents. This device provides an anastomosis clamp that has two eversion rings which are locked together by a series of impaling spikes on their opposing faces. However, this device is awkward for use in end-to-side anastomosis and tends to deform the target vessel; therefore it is not currently used in CABG surgery. Due to the delicate process needed to insert the vessels into the device, it would also be unsuitable for port-access surgery.

In order to solve these and other problems, it is desirable to provide an anastomosis device which performs an end-to-side anastomosis between blood vessels or other hollow organs and vessels. It is also desirable to provide an anastomosis device which minimizes the trauma to the blood vessels while performing the anastomosis, which minimizes the amount of foreign materials exposed to the blood flow path within the blood vessels and which avoids leakage problems, and which promotes rapid endothelialization and healing.. Further, it would be desirable to provide such a device which could be used in port-access CABG surgery. Whether it is used with open-chest or closed-chest surgical techniques, it is also desirable that the invention provide a complete system for quickly and automatically performing an anastomosis with a minimal amount of manual manipulation.

#### SUMMARY OF THE INVENTION

In keeping with the foregoing discussion, the present invention provides an anastomosis system for quickly and reliably performing an end-to-side vascular anastomosis. The anastomosis system includes an anastomosis device, an application instrument and methods for their use in performing an end-to-side vascular anastomosis. The system is especially useful for performing an anastomosis between a vascular graft and the wall of the ascending aorta in CABG surgery, particularly in port-access CABG surgery. One

desirable attribute of the anastomosis system is that the system should be as atraumatic as possible to the graft vessel in creating the anastomosis. Another desirable attribute of the anastomosis system is that the anastomosis device should minimize the amount of foreign material exposed to the blood flow path in the completed anastomosis. The anastomosis device of the system has a generally tubular or ring-shaped body having a proximal end and a distal end. An orifice or internal lumen in the body allows the graft vessel to pass through the device from the proximal end to the distal end. The body of the device has an attachment means at the distal end for attachment to the graft vessel, generally by everting the graft vessel over the attachment means. Means are provided for attaching the device and the graft vessel to the wall of the target vessel. Different embodiments of the anastomosis device are presented which vary in the form of the means used for attaching to the graft vessel and the target vessel.

A first aspect of the present invention takes the form of a vascular anastomosis staple device which may be used as part of an overall anastomosis stapling system and method designed to efficiently and reliably perform an end-to-side anastomosis between a graft vessel and the wall of a target vessel. The anastomosis staple device forms an atraumatic attachment to the end of the graft vessel so that only a smooth uninterrupted layer of intimal cells is exposed at the anastomosis site or within the graft vessel lumen. The anastomosis staple device creates a firm, reliable attachment between the graft vessel and the target vessel wall, with a tailored amount of tissue compression applied at the anastomosis site to form a leak-proof joint between the graft vessel and the target vessel wall. The anastomosis stapling system is designed to combine the various functions of graft vessel preparation, target vessel preparation, vessel approximation and anastomosis stapling into an integrated system of instruments so that the anastomosis can be performed efficiently with a minimum of manual manipulation of the vessels or the instruments involved. Different embodiments of

the anastomosis stapling system are provided to meet the needs of performing either a first anastomosis or a second anastomosis of a bypass procedure. The anastomosis stapling system is configured to be adaptable for closed-chest or port-access CABG surgery or for more conventional open-chest CABG surgery.

In one preferred configuration of the invention, the anastomosis staple device consists of two parts: an anchor member and a coupling member. The anchor member forms the attachment with the target vessel wall. The coupling member separately forms the attachment with the bypass graft vessel. The complete anastomosis is created when the coupling member, with the graft vessel attached, is inserted into the anchor member. In a second preferred configuration of the invention, the anastomosis staple device combines the functions of the anchor member and the coupling member into a single member. A one-piece anastomosis staple device attaches to both the target vessel wall and the graft vessel to form a complete end-to-side anastomosis. In all embodiments of the anastomosis staple device, certain desirable aspects are maintained, specifically the atraumatic attachment of the device to the graft vessel and the rapid, reliable formation of the anastomosis, as well as the adaptability of the staple device to port-access CABG surgery.

A second aspect of the present invention takes the form of an anastomotic fitting for attaching the end of a graft vessel to an opening formed in the side wall of a target vessel. The anastomotic fitting has an inner flange which provides an atraumatic attachment for the everted end of a graft vessel. The inner flange is configured so that, wherever possible, a smooth, continuous, uninterrupted layer of intimal tissue lines the graft vessel, the target vessel and the anastomotic site, with as little foreign material as possible exposed to the blood flow path. The outer flange contacts the exterior surface of the target vessel. A locking means, which may be part of the outer flange, locks the outer flange in a fixed position relative to the inner flange. The inner flange, in combination with the outer flange, provides a

firm attachment to the target vessel wall. A tailored amount of compression applied by the inner and outer flanges grips the target vessel wall and creates a leak-proof seal between the graft vessel and the target vessel. Optionally, attachment spikes on the surfaces of either the inner or the outer flange provide additional grip on the graft vessel and/or the target vessel. The attachment spikes are isolated from the blood flow lumens of the graft vessel and the target vessel so that they do not compromise the anastomotic seal or the structural integrity of the anastomotic attachment.

In a first representative embodiment, the anastomotic fitting is made up of two coacting parts: a) a tubular inner sleeve, which has an internal lumen of sufficient size to accommodate the external diameter of the graft vessel and an inner flange which is attached at the distal end of the inner sleeve, and b) an outer flange which has a central orifice that is sized to fit over the exterior of the inner sleeve. An adjustable locking mechanism holds the outer flange on the inner sleeve at a selected position to create a tailored degree of tissue compression at the anastomotic site.

The anastomosis procedure is performed by passing the end of the graft vessel through the inner lumen of the inner sleeve until the end of the vessel extends a short distance from the distal end of the sleeve. The end of the graft vessel is then everted over the inner flange of the fitting to form an atraumatic attachment. A loop of suture or spikes on the outside of the inner sleeve or flange may be added to help retain the graft vessel in its everted position. The inner flange and the everted end of the graft vessel are then passed through an opening that has previously been made in the wall of the target vessel with an instrument such as an aortic punch. The opening must stretch slightly to allow the inner flange to pass through. The elastic recovery of the target vessel wall around the opening helps to create an anastomotic seal by contracting around the inner sleeve and the everted graft vessel wall. The outer flange is then slid onto the proximal end of the inner sleeve. If the anastomosis

being performed is the first anastomosis on a free graft, such as a saphenous vein graft, then the outer flange can be slid over the graft vessel from the free end. If the other end of the graft vessel is not free, such as when performing the second anastomosis of a free graft or a distal anastomosis on a pedicled graft like the IMA, then the outer flange should be back loaded onto the graft vessel or preloaded onto the proximal end of the inner sleeve before the end of the graft vessel is attached to the inner flange of the fitting. The outer flange is slid down the inner sleeve until it contacts the exterior wall of the target vessel. A tailored amount of compression is applied to the anastomosis and the locking mechanism is engaged to complete the anastomosis.

A second representative embodiment of the anastomotic fitting has an expanding inner flange which facilitates the atraumatic attachment of the graft vessel to the fitting and makes it easier to pass the inner flange and the everted graft vessel through the opening in the target vessel wall. The graft vessel is passed through an internal lumen of an inner sleeve which has the expandable inner flange attached at its distal end. The end of the graft vessel is everted over the unexpanded inner flange. The inner flange and the everted end of the graft vessel are passed through the opening in the target vessel wall. Once the inner flange of the fitting is in the lumen of the target vessel, it is expanded to a diameter which is significantly larger than the opening in the target vessel wall. Then an outer flange is applied and locked into a selected position on the inner sleeve as described above to complete the anastomosis.

Different mechanisms are disclosed to accomplish the expansion of the inner flange. In a first variant of the expanding inner flange, the flange and a portion of the inner sleeve are slotted to create multiple fingers which are initially collapsed inward toward the center of the sleeve. A second inner sleeve is slidably received within the slotted inner sleeve. The graft vessel is inserted through the internal lumen of both sleeves and everted over the collapsed fingers of the flange. The collapsed flange is inserted

through the opening in the target vessel. Then, the second inner sleeve is slid distally within the slotted inner sleeve. The second inner sleeve forces the fingers outward, expanding the flange within the target vessel. The anastomosis is completed by applying the outer flange to the fitting as described above.

A second variant of the expanding inner flange has a slotted inner sleeve with multiple fingers that are oriented essentially longitudinally to the inner sleeve. Each of the fingers has a bend in it to predispose it to bend outward at the middle when under longitudinal compression. A tubular forming tool slidably received within the slotted sleeve is crenellated with multiple radially extending tabs. The radially extending tabs engage the distal ends of the fingers of the slotted inner sleeve. The anastomosis is performed by passing the graft vessel through the internal lumen of the fitting and everting it over the fingers. If desired, a loop of suture can be used to hold the everted vessel in place. The fingers of the fitting and the everted end of the graft vessel are inserted through an opening in the target vessel wall. When the tubular forming tool is slid proximally with respect to the slotted inner sleeve, the radially extending tabs bear against the distal ends of the fingers, compressing them longitudinally. The fingers bow outward, folding at the bend to expand and create an inner flange which engages the inner surface of the target vessel wall. In a preferred embodiment of this variation, the slotted inner sleeve has a proximal collar which captures the outer flange of the fitting so that the outer flange is applied simultaneously with the expansion of the inner flange. After the inner flange has been expanded, the tubular forming tool can be removed by rotating it with respect to the slotted inner sleeve so that the tabs align with the slots allowing it to be withdrawn from the fitting. This reduces the mass of foreign material that is left as an implant at the anastomotic site.

A third representative embodiment is a one-piece anastomotic fitting with an inner sleeve that is integrally attached to a fixed inner flange and to a deformable outer

flange. The anastomosis is performed by passing the graft vessel through the internal lumen of the inner sleeve and everting it over the inner flange. The inner flange and the everted end of the graft vessel are inserted through an opening in the wall of the target vessel. Then, the outer flange is deformed against the exterior surface of the target vessel wall with a tailored degree of tissue compression to complete the anastomosis. Two variants of the deformable outer flange are disclosed. The first variant has an outer flange that is divided into flange segments. The flange segments are attached to the inner sleeve by deformable hinges. The second variant has an outer flange in the form of a deformable hollow body. The hollow body is deformed against the exterior surface of the target vessel to complete the anastomosis.

The vascular anastomotic fitting is also part of a complete anastomosis system which includes instruments for applying the anastomosis fitting in a rapid, efficient and reliable manner to expedite the anastomosis process and to reduce the amount of manual manipulation necessary to perform the anastomosis. The application instrument has an elongated body with means at the distal end for grasping the anastomosis fitting and inserting the fitting into the chest cavity of a patient through an access port. The instrument includes an actuating means for deploying the inner and/or outer flange of the fitting to create the anastomosis. Variants of the instrument are specially adapted for each different embodiment and subvariation of the anastomosis fitting.

A third approach to expediting and improving anastomosis procedures used by the present invention combines the advantages of surgical stapling technology with other advantages of anastomotic fittings. Surgical stapling technology has the potential to improve anastomosis procedures over hand suturing techniques by decreasing the difficulty and complexity of the manipulations necessary and by increasing the speed and reliability of creating the anastomosis. The Kaster vascular staple in U.S. patent 5,234,447 overcomes one of the major limitations of the previous Kolesov stapling

device by allowing a stapled end-to-side anastomosis. This device, however, requires many delicate manual manipulations of the graft vessel and the staple while performing the anastomosis. This device therefore does not take full advantage of the time saving potential usually associated with stapling techniques.

The present invention attempts to marry the advantages of stapling approaches and anastomotic fitting approaches while carefully avoiding their potential drawbacks. As such, the present invention takes full advantage of the speed and reliability of stapling techniques, avoiding inasmuch as possible the need for complex manual manipulations. The invention also profits from the advantages of anastomotic fittings by providing a ring or flange that exerts even pressure around the anastomotic interface to eliminate potential leaks between the stapled attachments. The ring or flange also serves as a stent or support for the anastomosis site to prevent acute or long-term closure of the anastomosis. Inasmuch as possible the bulk of the fitting is kept on the exterior of the anastomosis so as to eliminate exposed foreign material in the bloodstream of the graft vessel or the target vessel. In most cases, only the narrow staple legs penetrate the anastomosis site, so that an absolute minimum of foreign material is exposed to the blood flow path, on the same order as the mass of suture exposed in a standard sutured anastomosis. The attachment technique for the anastomosis device eliminates the need to evert the graft vessel over a complex, irregular or sharp object such as the sharpened ends of the staple legs. Instead, a smooth ring or flange surface is provided for everting the graft vessel without damage or undue complication. The staple legs are separate or recessed within the flange to avoid potential damage to the graft vessel while attaching it to the device.

In a third aspect, the present invention takes the form of an anastomosis device which has a ring or flange to which the graft vessel attaches, typically by everting the graft vessel over the distal end of the ring. The ring or flange resides on the exterior of the graft vessel so that it

does not contact the blood flow path. A plurality of staple-like members attach the ring and the everted end of the graft vessel to the wall of the target vessel, which may be the aorta, a coronary artery or other vessel. An opening is created in the target vessel wall with an aortic punch or similar instrument to allow the target vessel lumen to communicate with the graft vessel lumen. The opening in the target vessel wall can be made before or after the device has been attached, depending on the application technique employed. In most of the examples disclosed, the staple members pierce the everted wall of the graft vessel and the wall of the target vessel to hold the two vessels together. Alternatively, the staple members may enter the lumen of the target vessel through the opening in the wall and then pierce the wall of the target vessel in the reverse direction. This variation pins together the vascular layers in the target vessel at the cut edge, potentially reducing the incidence of hemodynamically generated dissections in the wall of the target vessel.

Various configurations of the invention are disclosed which all exhibit the unifying characteristics of a cooperating ring or flange and a plurality of staple members. A first exemplary embodiment includes a ring-like fastening flange with deformable staple members for attaching the flange. A specially adapted staple applying device which operates through the lumen of the graft vessel is used to deform the staples to complete the anastomosis. A second embodiment includes a ring-like fastening flange with preformed, spring-like staple members. The elastic memory of the spring-like staple members holds the anastomosis tightly together. A family of embodiments includes a tubular fastening flange with U-shaped staple members and a locking means for fastening the staple members to complete the anastomosis. Another family of embodiments includes one or more ring-shaped fastening flanges with integrally formed staple members. Another family of embodiments includes a ring-like fastening flange with self-deploying staple members made of a superelastic metal alloy or a thermally activated

shape-memory alloy. A specially adapted staple applying device deploys the superelastic staple members. The specially adapted staple applying device together with the anastomosis device itself forms a total anastomosis system that is adaptable for either conventional open-chest CABG surgery or port-access CABG surgery.

Catheter devices are described which can be used as part of the total anastomosis system for isolating a portion of the target artery to facilitate performing the anastomosis procedure. One catheter device is configured to isolate a portion of the ascending aorta wall without occluding blood flow through the lumen of the aorta. A second catheter device is configured to be delivered by a transluminal approach for isolating a portion of a coronary artery during the anastomosis procedure. A third catheter device is configured to be delivered through the lumen of the graft vessel for isolating a portion of a coronary artery during the anastomosis procedure.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of the anchor member and the coupling member of a two-piece embodiment of the anastomosis staple device of the present invention.

Fig. 2 is a perspective view of a staple applier system for applying the anastomosis staple device of Fig. 1.

Fig. 3 is a perspective view of the distal end of the staple applier system of Fig. 2 showing the stapling mechanism and the vessel punch mechanism along with the anchor member of the two-piece anastomosis staple device of Fig. 1.

Fig. 4 is a cross sectional view of the distal ends of the stapling mechanism and the vessel punch mechanism of the staple applier system of Fig. 2 along with the anchor member of the two-piece anastomosis staple device of Fig. 1.

Figs. 5A-5G are side cross section view showing the sequence of operations for creating an end-to-side anastomosis with the two-piece anastomosis staple device of Fig. 1.

Figs. 6A is a perspective view of the graft insertion tool of the anastomosis staple applier system of

Fig. 2 prepared for insertion of the bypass graft with the coupling member of the two-piece anastomosis staple device. Figs. 6B-6C are side cross section and perspective views, respectively, of the distal end of the graft insertion tool of Fig. 6A.

Figs. 7A-7C are perspective, bottom end, and side cross section views, respectively, showing a variation of the graft insertion tool prepared for creating a second anastomosis of the bypass graft using the two-piece anastomosis staple device of Fig. 1.

Figs. 8A-8G are side views of various configurations of the attachment legs of the anchor member of Fig. 1 which allow for tailored amounts of tissue compression at the anastomosis site.

Fig. 9 is a perspective view of a one-piece embodiment of the anastomosis staple device of the present invention.

Fig. 10 is a cross sectional view of the one-piece anastomosis staple device of Fig. 9 being actuated to form an end-to-side anastomosis.

Fig. 11 is a cross sectional view of a one-piece anastomosis staple device with extended first segments on the staple legs.

Fig. 12 is a cross sectional view of a one-piece anastomosis staple device with secondary pivot points on the staple legs to create radial tissue compression.

Fig. 13 is a side cross sectional view of a staple applying tool for creating an end-to-side anastomosis using the one-piece anastomosis staple device of Fig. 9.

Fig. 14 is a cross sectional view of the distal end of the staple applying tool of Fig. 13 holding the one-piece anastomosis staple device of Fig. 9 with a graft vessel attached thereto.

Figs. 15A is a detail drawing of the female bayonet connector on the distal end of the anastomosis staple applying tool of Fig. 13. Fig. 15B is an end view of the male bayonet connector on the proximal end of the one-piece anastomosis staple device of Fig. 9.

Fig. 16 is a cross sectional schematic of another alternate embodiment of the one-piece anastomosis staple device being actuated to form an end-to-side anastomosis.

Fig. 17A-17B are a perspective views of a first alternate construction of the two-piece anastomosis staple device of Fig. 1. Fig. 17C is a cross section view of the anchor member of the anastomosis staple device of Fig. 17A attached to the wall of a target vessel. Fig. 17D is a cross section view of a completed anastomosis using the device of Fig. 17A-17B.

Figs. 18A-18F show a second alternate construction of the two-piece anastomosis staple device of Fig. 1.

Fig. 19A-19B shows a third alternate construction of the two-piece anastomosis staple device of Fig. 1.

Fig. 20 is a side cross section view of a fourth alternate construction of the two-piece anastomosis staple device of Fig. 1.

Figs. 21A-21C are side partial cross section views of a first embodiment of an anastomotic fitting according to the invention.

Figs. 22A-22C are side cross section views of an anastomosis fitting which is a variation of the embodiment of Figs. 21A-21C. Fig. 22D is a proximal end view of the anastomosis fitting of Fig. 22C.

Figs. 23A-23D are side cross section views of another variant of the embodiment of the anastomosis fitting of Figs. 21A-21C and Figs. 22A-22C.

Figs. 24A-24B are side cross section views of a second embodiment of the anastomotic fitting of the invention having an expanding inner flange. Figs. 24C and 24D are distal end views of the expanding inner flange in the collapsed position and the expanded position, respectively.

Figs. 25A-25H show a second variant of the anastomotic fitting with an expanding inner flange is shown in Figs. 24A-24D.

Figs. 26A-26I show a third embodiment which is a one-piece anastomotic fitting with a deformable outer flange.

Figs. 27A-27D show a second variant of the anastomotic fitting with a deformable outer flange.

Figs. 28A-28I show a third variant of the anastomotic fitting with a deformable outer flange.

5 Figs. 29A-29C show an embodiment of the anastomotic fitting having a secondary flange washer which attaches to the inner flange.

10 Figs. 30A-30K show an embodiment of the anastomotic fitting combining deformable inner staple members and an outer flange.

Figs. 31A-31F show a first embodiment of an anastomotic device combining a fastening flange with a plurality of staple members.

15 Figs. 32A-32F show an anastomosis device using preformed spring-like fastening staple members.

Figs. 33A-33D show an anastomosis device using S-shaped staple members that pierce the interior wall of the target vessel.

20 Figs. 34A-34D show an anastomosis device using S-shaped staple members that do not pierce the interior wall of the target vessel.

Figs. 35A-35F show an anastomosis device using U-shaped staple members with barbed points.

25 Figs. 36A-36C show an anastomosis device using U-shaped staple members and a locking collar.

Figs. 37A-37C show a second anastomosis device using U-shaped staple members and a locking collar.

30 Figs. 38A-38C show a one-piece anastomosis device with integral staple members.

Figs. 39A-39C show a second one-piece anastomosis device with integral staple members.

Figs. 40A-40D show a two-piece anastomosis device having two concentric ring flanges with integral staple members.

35 Figs. 41A-41E show an anastomosis device having a fastening flange and a plurality of individual staple members.

Figs. 42A-42D illustrate a one-piece embodiment of the anastomosis device with a fastening flange and attached staple members.

5 Figs. 43A-43B show the fastening flange of an anastomosis device using preformed superelastic alloy staple members in a top view and a side view, respectively.

Figs. 44A-44B show the superelastic alloy staple members of the anastomosis device in a front view and a side view, respectively.

10 Figs. 45A-45E show the sequence of operations of an application instrument for the anastomosis device of Figs. 43A-43B and Figs. 44A-44B.

15 Figs. 46A-46D illustrate a second embodiment of the anastomosis system using an anastomosis device with an inner fastening flange, an outer flange and staple members made of a superelastic alloy.

20 Figs. 47A-47B show an anastomosis staple device combining a fastening flange with precurved inner staple members of a highly resilient material and deformable outer attachment legs in an undeployed state.

Figs. 48A-48B show the anastomosis staple device of Figs. 47A-47B in a deployed state.

Figs. 49A-49C show the sequence of operations for deploying the anastomosis staple device of Figs. 47A-47B.

25 Figs. 50A-50B show a staple application instrument for applying the anastomosis staple devices of Figs. 47A-47B.

Fig. 51 shows a combination strain relief and compliance mismatch transition sleeve for use with any of the anastomosis devices of the present invention.

30 Fig. 52 shows a dual-balloon perfusion endoaortic clamp catheter for isolating a portion of the aortic wall while performing a proximal anastomosis in CABG surgery.

35 Fig. 53 shows a dual-balloon coronary isolation and perfusion catheter for use in performing a distal anastomosis in CABG surgery.

Fig. 54 shows a T-shaped dual-balloon coronary isolation and perfusion catheter for use in performing a distal anastomosis in CABG surgery.

Figs. 55, 56, 57 show the sequence of operations for creating an end-to-side anastomosis during port-access CABG surgery using the anastomosis stapling system of the present invention.

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#### DESCRIPTION OF THE PREFERRED EMBODIMENT

The invention will be now be described in detail with reference to the accompanying drawings. The detailed description describes the invention in relation to a proximal anastomosis during CABG surgery for joining the proximal end of the bypass graft to the aortic wall. This example is given by way of illustration only and is in no way meant to be limiting. Those skilled in the art will recognize that the anastomosis staple device and anastomosis stapling system of the present invention are readily adaptable for end-to-side connections of distal anastomoses (i.e. graft to coronary artery anastomoses) during CABG surgery, as well as for use on other blood vessels and other tubular organs within the body. For consistency and convenience, throughout the description the two ends of the anastomosis staple are referred to as the proximal and distal ends of the staple, the distal end of the staple being the end which is closest to the inner lumen of the target vessel and the proximal end being the free end which is farthest from the inner lumen of the target vessel.

Fig. 1 is a perspective drawing of a first embodiment of the anastomosis staple device of a first aspect of the present invention. The anastomosis staple device 100 consists of two parts: an anchor member 101, and a coupling member 102. The anchor member 101 forms the attachment to the exterior surface of the wall of a target vessel such as the aorta. The coupling member 102 forms the attachment to the bypass graft vessel. When the coupling member is joined to the anchor member, as shown by the dotted lines 103, it forms a complete anastomosis.

The anchor member 101 has a ring-shaped frame 104 which is configured to encircle an opening in the wall of a target vessel, such as the aorta. The ring-shaped frame 104 has a plurality of attachment legs 105, preferably six to

twelve, circumferentially spaced around the frame 104 and projecting from the distal end 106 of the ring. The anchor member 101 is preferably made of stainless steel or a titanium alloy for strength, biocompatibility and absence of MRI interference. The ring-shaped frame 104 and the attachment legs 105 preferably have a wall thickness of approximately 0.2 to 0.6 mm. The width of each of the attachment legs 105 is preferably between 0.5 and 2.0 mm. The attachment legs 105 could also be made with a round cross section to eliminate sharp edges which might propagate tears. The precise dimensions of the attachment legs 105 would be a compromise between making the legs rigid enough to pierce the wall of the target vessel without undue deformation, yet flexible enough to permit the stapling mechanism to deform the attachment legs after they have pierced the target vessel wall to hold the anchor member in place. These dimensions may vary depending on which vessel is chosen as the target vessel for the anastomosis.

The attachment legs 105 extend first radially outward from the ring 104, then there is a transition curve 107, after which the legs 105 extend axially away from the ring 104 in the distal direction. The transition curve 107 in each attachment leg 105 is shaped so that the anchor member 101 can be placed precisely on the target vessel wall, then affixed firmly in place with minimal displacement of the anchor member 101 or distortion of the target vessel wall. This attachment process will be described more fully in the operational description below.

The points of attachment between the attachment legs 105 and the ring-shaped frame 104 in this illustrative embodiment are all shown as being coplanar with one another. In other preferred embodiments, the distal extremity 106 of the anchor member 101 may be contoured to match the curvature of the exterior surface of the target vessel. Thus, the points of attachment between the attachment legs 105 and the ring shaped frame 104 will be arranged on a cylindrically curved surface which intersects the ring 104 of the anchor member 101 rather than a plane. This would be especially

important when there is closer parity between the diameter of the graft vessel and the diameter of the target vessel, such as when performing a distal anastomosis between a venous or arterial graft and a coronary artery, because a planar arrangement of the attachment legs 105 would not approximate the curvature of the target vessel wall as well as for a larger target vessel such as the aorta. In other alternate embodiments, the distal end of the anchor member 106 and the attachment legs 105 may be angled with respect to the ring-shaped frame 104 to permit an angled takeoff of the graft vessel from the target vessel.

One preferred configuration for the transition curve 107 in the attachment legs 105 is illustrated in Fig. 1. The first segment 108 of each attachment leg extends radially from the ring-shaped frame for a short distance. The second segment 109 of each leg angles proximally from the first segment at approximately 60° for a short distance. Then, the third segment 110 angles approximately 60° in the distal direction from the second segment 109. The fourth segment 111 extends in the distal direction from the third segment 110 so that the fourth segment 111 extends axially away from the ring-shaped frame 104 parallel to the central axis of the ring 104. The second 109 and the third 110 segments should be approximately equal in length to one another. The actual length of the second 109 and third 110 segments will be determined by the wall thickness of the target vessel. A typical length of 1.5-5 mm would be used for attachment to the wall of the aorta. The distal ends 112 of the attachment legs 105 are sharpened to easily penetrate the aortic wall.

This illustrates just one preferred transition curve 107 for the attachment legs 105. Alternate transition curves 107 for the attachment legs 105 may include arc-shaped segments in place of some of the straight segments or may include a greater number of straight segments to approximate a smoother curve. When choosing alternate curves, it is important to preserve the axially extending final segment 111 of the attachment legs in order to penetrate the target vessel wall. In addition, it is important to control the amount of

distortion of the target vessel wall when the anchor member 101 is attached. This is in contrast to many standard wound closure staples which deliberately bunch up the tissue when they are applied to create a closer approximation of the tissues being joined. This type of distortion may be counterproductive in attaching a graft vessel to the aortic wall because the wall may be too stiff to distort in this manner and the distortion might cause problems in creating a leak proof seal at the anastomosis. The anvil geometry of the stapling mechanism will also be important in determining the optimum geometry of the attachment legs.

The amount of radial compression of the target vessel wall around the anastomosis can be tailored by the choice of the transition curve 107 in the attachment legs 105 of the anchor member 101. Radial compression of the target vessel wall around the anastomosis helps to create and maintain an anastomotic seal between the target vessel and the graft vessel in the completed anastomosis. This is especially important when blood pressure is restored in the target vessel which will tend to stretch the target vessel wall and pull it away from the anastomosis. The radial compression by the attachment legs counteracts this expansion and maintains the anastomotic seal under pressure. Fig. 8A-8G show various other possible geometries for the attachment legs 105 of the anchor member 101 arranged according to the degree of tissue compression applied to the target vessel wall. Fig. 8A shows a staple attachment leg 105 where the transition curve 107 consists of a straight second segment which extends upward at ninety degrees from the first radially extending segment. The third segment 110 describes a 90° arc with a center of rotation at the transition point between the first 108 and second 109 segments. The fourth segment 111 extends straight in an axial direction from the third segment 110. This embodiment of the attachment legs 105 creates very little tissue compression when applied. The amount of tissue compression is indicated by the shaded region between the straight insertion path of the fourth segment 111 and the final position of the actuated staple shown in phantom lines

105. Fig. 8B shows a transition curve 107 with an elliptically shaped second segment 109 which smoothly evolves into an arc-shaped third segment 110 with a center of rotation at the transition point between the first 108 and second 109 segments. This embodiment creates a slightly greater degree of tissue compression. Fig. 8C shows an attachment leg geometry which is formed entirely of smooth curves so as to avoid any sharp bends in the attachment legs 105, but which produces approximately the same tissue compression as the attachment leg of Fig. 8B. Fig. 8D shows a transition curve 107 with a 30° arc-shaped second segment 109 connecting to a 30° arc-shaped third segment 110 with a center of rotation at the transition point between the first 108 and second 109 segments. Fig. 8E shows a side view of the embodiment illustrated and described above in Fig. 1. The second segment 109 angles 60° upward from the first segment 108, and the third segment 110 angles downward at 60° from the second segment 109. This produces a selected degree of tissue compression when the attachment legs 105 are actuated. Fig. 8F shows an attachment leg geometry which produces slightly greater tissue compression in the target vessel. The second 109 and third 110 segments of the transition 107 are smoothly blended together in a continuous semicircular arc. Fig. 8G shows an attachment leg geometry which produces even more tissue compression. The second segment 109 angles upward at 45° from the first segment 108 and the third segment 110 angles downward from the second 109 at a 90° angle. Many other attachment leg geometries may be tailored to produce the desired degree of tissue compression in the target vessel.

The coupling member 102, as seen in Fig. 1, has a tubular body 113 with a passage 114 through it. The distal end of the coupling 102 has an atraumatic edge 115 over which the graft vessel will be everted in forming the anastomosis. The atraumatic edge 115 is important to avoid piercing or damaging the vessel wall in the vicinity of the anastomosis which occurs with some prior art devices. Atraumatic attachment of the graft vessel to the coupling member helps to assure a reliable anastomotic seal between the graft vessel

and the target vessel and reduces the likelihood of mechanical failure of the graft vessel wall due to punctures or tears in the wall. The exterior of the coupling member 102 is sized to fit into the interior of the ring-shaped frame 104 of the anchor member with enough space between them to accommodate one wall thickness of the bypass graft. The coupling member 102 is preferably made of stainless steel, a titanium alloy or plastic with a wall thickness of approximately 0.1 to 0.6 mm. The exterior of the coupling member 102 has exterior surface features 116 which serve a dual purpose. The exterior surface features 116 serve to hold the everted end of the bypass graft onto the coupling member 102, as well as to interlock the coupling member 102 with the anchor member 101 to complete the anastomosis. Likewise, the interior of the anchor member 101 is made with interior surface features 117 which interact with the exterior surface features 116 to create the interlock. The exterior surface features 116 of the coupling member 102 could be in the form of bumps, pins, points, barbs, ridges, threads, holes or a combination of these features. The interior surface features 117 of the anchor member 101 would then be in the form of corresponding bumps, pins, points, barbs, ridges, threads or holes to lock the two parts together. It should be noted that, if pins, points, barbs or other piercing members are used as the interior 117 or exterior 116 surface features of the anastomosis staple device 100, these potentially traumatic features are located away from the everted edge of the graft vessel and outside of the lumens of the graft vessel and target vessel that will serve as the conduit of the bypass so as not to compromise the integrity of the anastomosis.

In the embodiment illustrated, the coupling member 102 is shown with bump-shaped exterior surface features 117 that hold the everted graft vessel onto the coupling member 102 and interlock with a series of circumferential ridges 116 within the anchor member 101. The interior ridges 116 of the anchor member 101 permit a variable degree of engagement between the coupling member 102 and the anchor member 101 to allow for different wall thicknesses of the target vessel and

the graft vessel used in the anastomosis. The axial position of the coupling member 102 with respect to the anchor member 101 can be varied to create the desired degree of axial tissue compression to assure an anastomotic seal despite variations in the vessel wall thicknesses.

The complete anastomosis stapling system includes the anastomosis staple device 100 and an instrument 118 for applying the anastomosis staple 100. The instrument 118 for applying the two-part anastomosis staple 100 consists of three separate, but interacting, mechanisms: a stapling mechanism 119, a vessel punch mechanism 120, and a graft insertion tool 121, 122. Together with the anchor member 101 and the coupling member 102, they comprise a complete system for performing an anastomosis. In Fig. 2, we can see two of these mechanisms, the stapling mechanism 119 and the vessel punch mechanism 120, assembled together with the anchor member 101 of the anastomosis staple 100, prepared for the first stage of the anastomosis procedure. The third mechanism, the graft insertion tool, is shown in two different embodiments 121, 122 in Figs. 6A-6C and Figs. 7A-7C, respectively.

The stapling mechanism 119 and the vessel punch 120 are shown assembled together in a perspective view in Fig. 2. The anchor member 101 of the anastomosis staple 100 is held by the staple retainer 123 on the distal end of the stapling mechanism. This same assembly can be seen in cross section in the operational drawings 5A-5C. The distal end of this assembly is shown in greater detail in cross section in Fig. 4. The stapling mechanism 119 has an inner tube 124 and an outer tube 125 which are threaded together at their distal ends. The outer tube 125 has a handle 126 at the proximal end and an annular staple driver 127 at the distal end of the tube. The inner tube 124 has a staple retainer 123 for holding the anchor member 101 of the anastomosis staple 100 on the distal end of the tube. The inner tube 124 has an internal lumen 128 of sufficient size to accommodate the vessel punch mechanism 120 and the graft insertion tool 121, alternately. The proximal end of the inner tube 124 has a pair of opposing slots 129 on the inner surface that act as

splines for engagement with a corresponding pair of lugs 130, 134 on the exterior of the vessel punch mechanism 120 and on the graft insertion tool 121.

The vessel punch mechanism 120 is sized to fit through the internal lumen 128 of the inner tube 124 of the stapling mechanism 119. The vessel punch mechanism 120 has an outer tube 131 and an inner drive member 132 slidably received within the outer tube. The proximal end of the outer tube 131 is attached to a T-shaped handle 133. The outer tube 131 has a pair of lugs 130 near the proximal end which extend radially from the exterior of the tube 131 to engage the opposing slots 129 in the inner tube 124 of the stapling mechanism 119. The distal end of the outer tube 131 tapers to form a neck 135 which attaches to a cutter anvil 136. The vessel punch cutter 137 is a tubular member which slides telescopically on the distal end of the outer tube 131 of the vessel punch 120. The distal edge 138 of the tubular cutter 137 is sharpened with an approximately conical bevel 138. The outer tube 131 of the vessel punch mechanism 120 may include a step 139 against which the cutter is located in the retracted position as in Figs. 5A and 5B. The tubular cutter 137 is attached to the drive member by a transverse pin 140 which extends through a pair of opposing slots 141 in the distal end of the outer tube 131. The proximal end of the drive member 132 is attached to an actuating plunger 142 which extends proximally of the T-shaped handle 133.

The vessel punch mechanism 120 is actuated by pressing on the actuating plunger 142 to move it with respect to the T-shaped handle 133. This linear motion is transferred to the inner drive member 132 and then, in turn, to the tubular cutter 137 by way of the transverse pin 140. The tubular cutter 137 slides forward until the inner lumen of the cutter 137 slides over the anvil 136 in a shearing action. There is a very tight clearance between the inner lumen of the cutter 137 and the outer diameter of the anvil 136. This tight clearance assures a cleanly cut hole through the vessel wall without ragged or torn edges. In Fig. 5C, the vessel

punch mechanism 120 is shown actuated to cut a hole through the aortic wall tissue.

Fig. 3 is a large scale perspective detail drawing of the distal end of the vessel punch mechanism 120 assembled with the stapling mechanism 119. The anchor member 101 of the anastomosis staple 100 is held by the staple retainer 123 on the distal end of the inner tube 124 of the stapling mechanism 119. The ring-shaped frame 104 of the anchor member 101 fits inside of a counterbore 143 on the distal end of the inner tube, as can be seen in Figs. 4 and 5A-5E. The attachment legs 105 of the anchor member 101 are captured and held by the L-shaped gripping fingers 144 which extend from the distal end of the inner tube 124. There are an equal number of gripping fingers 144 on the inner tube 124 as there are attachment legs 105 on the anchor member 101. Each gripping finger 144 has an axial slot 145 alongside of it which is at least as wide as the attachment legs 105. The axial slot 145 connects with a transverse slot 146 in the side of each gripping finger 144. The anchor member 101 of the anastomosis staple 100 is loaded onto the staple retainer 123 by aligning the attachment legs 105 with the ends of the axial slots 145, pushing the attachment legs 105 to the bottom of the axial slots 145, then turning the anchor member 101 counterclockwise until the attachment legs 105 enter the transverse slots 146 in the side of the gripping fingers 144. The anchor member 101 can be secured in this position by rotating the outer tube 124 of the stapling mechanism to advance it distally until the staple driver 127 contacts the attachment legs 105 with enough force to hold the anchor member 101 in place without deforming the legs. Alternatively, the inner tube 124 of the stapling mechanism 119 could be adapted to grip the ring-shaped element 104 of the anchor member 101 directly.

The T-shaped handle 133 of the vessel punch mechanism 120 also serves as the handle for the inner tube 124 of the stapling mechanism 119 at this stage of the procedure because the lugs 130 on the exterior of the vessel punch outer tube 131 engage the slots 129 in the interior of the stapler inner tube 124. Likewise, in the latter stages of the

procedure, the T-shaped handle 133 of the graft insertion tool 121 can also serve as a handle for the inner tube 124 of the stapling mechanism 119 because the lugs 134 of the graft insertion tool 121 engage the inner slots 129 of the stapler inner tube 124 in a similar fashion. Alternatively, the inner tube 124 of the stapling mechanism may be supplied with a separate handle or knob of its own so the inner 124 and outer 125 tubes of the stapling mechanism can be rotated with respect to one another to operate the stapling mechanism when neither the aortic punch mechanism 120 nor the graft insertion tool 121 is inserted into the stapling mechanism 119.

A first embodiment of the graft insertion tool 121 and its relationship to the coupling member 102 of the anastomosis staple 100 are shown in detail in Figs. 6A-6C. This embodiment of the graft insertion tool 121 may be used when the anastomosis staple 100 is used to form the first anastomosis of the bypass procedure no matter whether the first anastomosis is the proximal or the distal anastomosis of the graft. To prepare the bypass graft for creating the anastomosis, the coupling member 102 is first loaded onto the distal end of the graft insertion tool 121. A shoulder 147 on the graft insertion tool 121 holds the coupling member 102 in the correct position, and a tight interference fit or a spring action prevents it from inadvertently falling off. The graft vessel 148 is then loaded into the internal lumen 149 of the graft insertion tool 121. This can be done by tying a suture around the graft vessel on the end opposite to the end that will be anastomosed, passing the suture through the internal lumen 149 of the graft insertion tool 121, then drawing the graft vessel 148 into the lumen until the end 192 of the graft vessel 148 to be anastomosed extends a short distance from the distal end of the graft insertion tool 121. Alternatively, a special tool, such as a narrow pair of endoscopic forceps or a nerve hook, may be used for grasping the graft vessel 148 and drawing it through the graft insertion tool 121. At this point, the end 192 of the graft vessel 148 to be anastomosed is everted over the end of the graft insertion tool 121 and the coupling member 102, as shown in Figs. 6A-6C. The

external surface features 116 of the coupling member 102 serve to hold the graft vessel onto the exterior of the coupling member 102 in the everted position. The external surface features 116 of the coupling member may at least partially penetrate the wall of the graft vessel 148 to provide greater holding force.

With the anchor member 101 loaded onto the stapling mechanism 119 and the graft vessel 148 prepared by everting and attaching it to the coupling member 102 as described above, the device is ready to perform the end-to-side anastomosis, as illustrated in Figs. 5A-5G. Referring now to Fig. 5A, the stapling mechanism 119 and the vessel punch mechanism 120 are shown assembled together. A slit 150 is made in the target vessel wall 150 with a scalpel or other sharp instrument, and the anvil 136 of the vessel punch 120 is inserted through the slit 151 into the lumen of the target vessel 150. The anvil 136 serves to center the stapling mechanism 119 and the anchor member 101 around the chosen attachment point on the target vessel 150 where the slit 151 is made. The stapling mechanism 119 is advanced over the vessel punch mechanism 120 toward the wall of the target vessel 150, as shown in Fig. 5B. A slight tension is maintained on the T-handle 133 of the vessel punch mechanism 120 so that the anvil 136 supports the wall of the target vessel 150 as the attachment legs 105 of the anchor member 101 contact and penetrate the target vessel wall 150. The fourth segments 111 of the attachment legs 105 penetrate the target vessel wall 150 in a linear path. Once the fourth segments 111 of the attachment legs 105 have traversed the target vessel wall 150, the attachment legs 105 are actuated, as shown in Fig. 5C. The outer tube 125 of the stapling mechanism 119 is advanced over the inner tube 124 by rotating the handle 126 of the outer tube 125 with respect to the T-handle 133 of the vessel punch mechanism 120. This advances the staple driver 127 against the attachment legs 105, deforming them into the position shown in Fig. 5C. After the attachment legs 105 have been actuated, the tubular cutter 137 of the vessel punch mechanism 120 is advanced with respect to

the anvil 136, as shown in Fig. 5D, by pressing on the actuating plunger 142 at the proximal end of the drive member 132. The punch mechanism 120 creates an opening 152 through the target vessel wall 150. The vessel punch mechanism 120 with the tissue 153 that was excised by the punch can now be withdrawn from the inner lumen 128 of the stapling mechanism 119, as shown in Fig. 5E, leaving the anchor member 101 attached to the target vessel wall 150 in alignment with the opening 152 punched therein.

The graft vessel insertion tool 121 with the prepared graft vessel 148 and coupling member 102 in place is inserted into the inner lumen 128 of the stapling mechanism 119 as shown in Fig. 5F. The coupling member 102 is pressed into the ring-shaped frame 104 of the anchor member 101 and the exterior features 116 on the coupling member 102 engage the interior features 117 of the ring-shaped frame 104 to hold the coupling member 102 and the anchor member 101 together. The staple retainer 123 of the stapling mechanism 119 still has a firm grasp on the anchor member 101 to provide support as the coupling member 102 is pressed into the ring-shaped frame 101. The coupling member 102 should be pressed into the ring-shaped frame 104 until the everted end of the graft vessel 148 bears against the exterior surface of the target vessel wall 150, creating a fluid tight seal at the anastomosis site. Alternatively, the coupling member 102, with the everted end of the graft vessel 148 attached, can be made to extend into the opening 152 in the target vessel wall 150 with the target vessel wall 150 creating a radial compression around the graft vessel 148 and the coupling member 102. The stapling mechanism 119 can now be disengaged from the anchor member 101 by turning the handle 126 of the outer tube 125 with respect to the T-handle 133 of the graft insertion tool 121 until the staple driver is withdrawn from the attachment legs 105. Then the inner tube 124 of the stapling device can be turned counterclockwise by turning the T-shaped handle 133 of the graft insertion tool 121 to disengage the gripping fingers 144 of the staple retainer 123 from the attachment legs 105 of the anchor member 101. A

complete end-to-side anastomosis, as shown in Fig. 5G, is left at the anastomosis site.

It should be noted that the order of the steps of the anastomosis procedure 127 could be altered. For instance, the opening could be first punched in the target vessel with an aortic punch or similar instrument, and then the anchor member of the staple could be attached. In this instance, the graft vessel could be attached to the anchor member either before or after the anchor member is attached to the target vessel. Other variations in the order of the steps are also possible.

Fig. 7A shows a perspective drawing of a second embodiment of the graft insertion tool 122 for use in performing the second anastomosis on a graft vessel, one end of which has already been anastomosed, or for other situations when both ends of the graft vessel are not available, such as when making the distal anastomosis on an internal mammary artery bypass graft. This embodiment of the graft insertion tool 122 is made with a two-part, hinged holder 154 for the coupling member of the anastomosis staple device so that the holder 154 can be removed from around the graft vessel 148 after both ends of the graft have been anastomosed. The holder 154 is attached to the distal end of a tubular member 155 which is attached on its proximal end to a handle grip 156. A shaft 157 is slidably received within the tubular member 156. The distal end of the shaft 157 is attached to a U-shaped yoke 158 which is configured to grip a flange 159 or a pair of lugs on the proximal end of the anchor member 101. The handle grip 156 has a coacting trigger member 160 which is attached to the proximal end of the shaft 157 through a slot 161 in the side of the tubular member 155. The holder 154 is spring biased toward the open position 154'. The force of the spring action helps the holder 154 to grip the coupling member 102 so that it does not slip off of the holder 154 prematurely. A distal end view of the holder 154 is shown in Fig. 7B, with the holder 154 shown in both the closed position and the open position (phantom lines 154').

To prepare the graft vessel 148 for the anastomosis, the coupling member 102 is first placed onto the holder 154 and the end of the graft vessel 148 to be anastomosed is passed through the lumen 162 of the holder 154 and the coupling member 102 from the proximal to the distal end. The end of the graft vessel 148 is then everted back over the coupling member 102, as shown in Fig. 7C. The external surface features 116 on the coupling member 102 will hold the everted vessel in place on the coupling member. In figure 7C, the anchor member 101 of the anastomosis staple device 100 has been fastened to the target vessel 150, as described above in relation to Figs. 5A-5E, and the stapling mechanism 119 has been removed by turning the handle 126 of the stapling mechanism 119 counterclockwise relative to the handle 126 on the vessel punch mechanism 120 until the anchor member 101 is released. The graft insertion tool 122 with the prepared graft vessel 148 is now positioned at the anastomosis site and the U-shaped yoke 158 is used to grip the anchor member 101, retained by the flange 159 on its proximal end. With the graft vessel 148 and the coupling member 102 aligned with the anchor member 101 as shown, the handle grip 156 and the trigger 160 are squeezed together to press the coupling member 102 into the anchor member 101 until the everted end of the graft vessel 148 is pressed against the outer surface of the target vessel 150 creating a leak-proof anastomosis. The holder 154 is then retracted from the coupling member 102 by moving the trigger 160 away from the handle grip 154. The hinged holder 154 opens when it is withdrawn from the coupling member 102, releasing the graft vessel 148 from the lumen 162 of the holder 154. The U-shaped yoke 158 can now be slid sideways off of the anchor member and the anastomosis is complete.

A one-piece version of the anastomosis staple device of the present invention along with a specially adapted staple applying tool will now be described in detail. In the one-piece embodiments which follow, a tubular member, analogous to the coupling member of the previously described embodiment, is permanently attached to a circular staple

member, which is analogous to the anchor member 101 of the previously described embodiment.

Fig. 9 shows a perspective view of a first embodiment of the one-piece anastomosis staple device 163 of the present invention. This same embodiment is shown in cross section in Figs. 11 and 13. The anastomosis staple 163 has a tubular body member 164 which has an inner lumen 165 sized to accommodate the exterior diameter of the graft vessel 148. Means for attaching the graft vessel 148 are provided at the distal end of the tubular body member 164 or on the outside of the tubular member 164. In the preferred embodiment, the means for attaching the graft vessel 148 to the anastomosis staple 163 is a tubular distal extension 166 of the tubular body over which the graft vessel 148 is everted. The tubular extension 166 may include a flange 167 to secure the attachment of the everted graft vessel 148 to the tubular extension 166. This flange 167 may also engage the inner surface of the target vessel 150 to help retain the graft 148 in place.

The anastomosis staple device 163 has a multiplicity of staple legs 168 extending from the tubular body member 164 proximal to the tubular distal extension 166. Optionally, the tubular body member 164 may extend proximally 169 from the staple legs 168 as shown, or the tubular body member can be truncated at or near the level of the staple legs to decrease the overall profile of the staple. The optional proximal extension 169 of the tubular body member 164 may include lugs or tabs 170 or a flange or other features that can be used for gripping the staple 163 by a staple applying tool.

The anastomosis staple 163 typically has five to twelve staple legs 168 for attaching to the target vessel wall 150. The presently preferred embodiment of the staple 163 has six staple legs 168 as illustrated in Fig. 9. The staple legs 168 are distributed circumferentially around the exterior of the tubular body member 164. The staple legs 168 can be formed integrally with the tubular body member 164, or they can be manufactured separately and attached to the tubular body member 164. Optionally, the exterior of the tubular body

member 164 may include a circumferential ledge 171 to which the staple legs 168 are attached. In the pre-actuated position, the legs 168 angle proximally from where they attach to the tubular body member 164 so that the sharpened tips 172 of the staple legs are proximal to the point of attachment with the body. The staple legs 168 have a first segment 173 which extends approximately straight from the tubular body member; then there is a transitional segment 174 and a curved end segment 175. The curved end segment 175 of each staple leg has a sharpened tip 172 for easily piercing the wall of the target vessel 150. The curve of the end segment 175 is a circular arc whose center of rotation coincides approximately with the point of attachment 176 between the staple leg and the tubular body member. The point of attachment 176 serves as a pivot point for the staple leg 168 when it is actuated, so that the end segment 175 of the staple legs 168 describes an arc-shaped path through the tissue of the target vessel wall that follows the curvature of the arc-shaped end segment 175.

The transition segment 174 of the staple legs 168 can take on one of several forms depending on the effect desired in the actuated staple. If the transition segment 174 is largely a right-angle bend, so that only the end segment 175 penetrates the tissue, then the staple legs 168 will cause very little radial compression of the target vessel wall tissue 150 as the staple 163 is actuated. If, on the other hand, the transition segment 174 has a curve of smaller radius than that of the curved end segment 175, the tissue will be compressed and pulled toward the tubular body member 164 as the transition segment 174 enters and travels through the target vessel wall 150, as illustrated in Fig. 10. The degree of radial tissue compression can be regulated to the appropriate amount by proper design of the curve in the transition segment 174 of the staple legs 168. In addition, the shape of the first segment 173 may help to define the surface shape of the target vessel 150 after the staple 163 is applied. It may be desirable to keep it as flat as possible, or it may be desirable to "tent up" the target vessel somewhat

in the area of the anastomosis. Optionally, the first segment may be given greater effect on the target vessel surface shape by extending the first segment 173 beyond the transition point with the second segment 174, as shown in Fig. 11. The  
5 straight extension 177 of the first segment 173 beyond the attachment point of the transition curve 174 will tend to flatten out the tissue of the target vessel wall 150 at the anastomosis site so that undue deformation of the vessel wall does not compromise the integrity of the anastomosis.

10 Fig. 12 shows another means for accomplishing the tissue compression performed by the transition segment 174 of the staple legs 168 in the embodiment of Figs. 9 and 10. In this embodiment, the transition segment 174 of the staple legs 168 is essentially a right angle bend with very little  
15 radius, so the staple legs 168 cause very little tissue compression as they pierce the target vessel wall 150 and travel through the tissue. However, before the staple legs 168 have reached the end of their travel, the first segment 173 comes into contact with a circumferential ledge 178 that  
20 extends outward from the tubular body member 164 just below the attachment point 176 of the staple legs 168. When the staple legs 168 contact the ledge 178, the first segments 173 of the legs bend where they contact the outer edge of the ledge 178. This moves the center of rotation outward and  
25 shortens the radius of rotation of the curved end segment 175 so that the staple legs will pull the tissue of the target vessel wall 150 toward the tubular body member 164, compressing the tissue.

The staple legs 168 are preferably dimensioned so  
30 that the staple legs travel all the way through the target vessel wall 150 when the staple is actuated. In the embodiment of Fig. 10, after actuation, the ends 172 of the staple legs 168 rest just distal to the flange 167 on the distal end 166 of the tubular body member 164. In the  
35 embodiment of Fig. 12, the staple legs 168 are configured to pierce the wall of the graft vessel 148 just proximal to the flange 167 on the distal end 166 of the tubular body member 164, adding to the security of the attachment. In both

embodiments the flange 167 supports the tissue of the target vessel wall 150 as the ends 172 of the staple legs 168 emerge, helping to insure that the staple legs 168 will pierce cleanly through the target vessel wall 150 without separating the lamina, which could lead to dissection. In both cases, the staple legs 168 are configured so that the curved end segments 175 of the staple legs 168 are driven all the way through the target vessel wall 150 before there is significant compression of the tissues. The tubular body member 164 isolates the cut edge at the opening 152 in the target vessel wall 150 from the blood flow path so that blood pressure will not cause delamination of the target vessel wall 150. The staple legs 168, the tubular body member 164 and the flange 167 form a closed loop, similar to a sutured attachment. These factors also help to minimize the danger of dissection of the target vessel wall 150.

Fig. 13 shows one preferred embodiment of the one-piece anastomosis staple 163 mounted on the distal end of a specially adapted staple applying tool 179. The staple applying tool 179 has an outer tube 180 and an inner tube 181 slidably received within the outer tube 180. The inner tube 181 has an inner lumen 182 of sufficient diameter to accommodate the outer diameter of the graft vessel 148 that will be used for the anastomosis. The staple applying tool 179 has a main body 183 which is shaped in the form of a pistol grip. The proximal end of the inner tube 181 is anchored with respect to the main body 183 by a flange 184 or other attachment on the proximal end. The outer tube 180 is slidable with respect to the inner tube 181 by actuating the lever 185 of the staple applying tool 179 which engages a pair of pins 186 attached to the exterior of the outer tube. Pulling the lever 185 advances the outer tube 180 distally over the inner tube 181. A return spring 187 attached to the lever 185 returns the lever 185 and the outer tube 180 to their unactuated positions.

A close-up view of the anastomosis staple 163 and the distal end of the staple applying tool 178 is shown in Fig. 14. The anastomosis staple 163 in this embodiment has a

tubular body 164 which is permanently attached to a plurality of circumferentially distributed attachment legs 168. The tubular body 164 has a distal tubular extension 166 with a flange 167 for eversion and attachment of the graft vessel 148. There is also a proximal tubular extension 169 which has a pair of tabs 170 for grasping the staple with a staple retainer 188 on the distal end of the inner tube 181 of the staple applying tool 179. An end view of the tabs 170 is shown in Fig. 15A. The staple retainer 188 at the distal end of the inner tube 181 shown in detail in Fig. 15B, has a pair of longitudinal slots 189 corresponding to the two tabs 170 of the anastomosis staple. Connected to the longitudinal slots 189 is a circumferential groove 190 within the inner tube 188. The staple 163 is attached to the staple retainer 188 by aligning the tabs 170 with the longitudinal slots 189 and sliding the tabs into the slots 189. When the tabs 170 reach the bottom of the longitudinal slots 189, the staple 163 is rotated with respect to the inner tube 181 so that the tabs 170 enter the circumferential groove 190. A ridge 191 on the distal side of the groove 190 holds the tabs 170 within groove 190 to retain the staple 163 on the end of the inner tube 181.

It should be noted that a number of methods of attaching the tubular member 164 to the stapling mechanism 179 are possible besides the bayonet attachment illustrated. The end of the stapling mechanism 179 may be configured to grasp the tubular member 164 on the inner diameter or the outer diameter distal to the point of attachment 176 of the staple legs 168, allowing the proximal tubular extension 169 of the anastomosis staple 163 to be eliminated. This modification would allow a lower profile anastomosis attachment to be created.

To prepare the graft vessel 148 for anastomosis, an anastomosis staple 163 is attached to the distal end of the staple applying tool 179 as just described, then, using a suture or an elongated grasping tool, the graft vessel 148 is drawn into the inner lumen 182 of the tool until the end 192 of the graft vessel 148 to be anastomosed extends a short distance from the distal end of the tool. At this point, the

end 192 of the graft vessel 148 to be anastomosed is everted over the distal tubular extension 166 and the flange 167 as shown in Fig. 14. A suture can be tied around the everted end 192 of the graft vessel 148 proximal to the flange 167 to retain the graft vessel 148 on the staple 163, if desired.

Thus prepared, the staple 163 is advanced toward an opening 152 that has been previously made in the target vessel wall 150 with an aortic punch or other appropriate tool.

Preferably, the opening 152 is made with a diameter approximately equal to the outer diameter of the distal tubular extension 166 of the staple 163 just proximal to the flange 167. The flange 167 with the everted end 192 of the graft vessel 148 is passed through the opening 152 in the target vessel 150, as shown in Fig. 10. The target vessel wall 150 may need to be stretched slightly to allow the flange 167 to pass through the opening 152. The elastic recovery of the target vessel wall 150 creates a compressive force where the target vessel wall 150 surrounds the distal tubular extension 166 with the everted end 192 of the graft vessel 148 which contributes to the fluid-tight seal of the anastomosis.

Once the flange 167 has been passed through the opening 152 in the wall of the target vessel 150, the anastomosis staple 163 is pulled back slightly so that the flange 167, covered by the everted graft vessel wall 192, is against the inner surface of the target vessel wall 150. Then, the staple 167 is actuated by pulling on the lever 185, which moves the outer tube 180 distally until the staple driver 193 at the distal end of the outer tube 180 bears on the attachment legs 168. As the staple driver 193 advances, the attachment legs 168 bend at the fulcrum 176 where they attach to the tubular member 164. The arc-shaped third segments 175 of the attachment legs 168 penetrate and traverse the wall of the target vessel 150. Once the third segments 175 of the attachment legs 168 have traversed the wall, the staple 163 begins to compress the tissue of the target vessel wall 150 radially against the distal tubular extension 166 of the anastomosis staple 163 by any of the mechanisms previously discussed. After the attachment legs 168 of the anastomosis

staple 163 have been fully actuated, the lever 185 is released and the staple applying tool 179 is rotated to disengage the staple retainer 188 from the tabs 170 on the proximal tubular extension 169 of the staple 163. The staple applying tool 179 is withdrawn and the anastomosis is complete.

Fig. 16 shows another potential configuration for the staple legs 194 of the one-piece anastomosis staple 195. In this embodiment, the staple legs 194 have a compound curved transition segment 197 which provides two different axes of rotation for the staple legs 194 as they are actuated. The staple legs 194 attach to the proximal end of the tubular body member 198. A first segment 199 of the staple leg 194 extends approximately radially from the point of attachment 206. There is a U-shaped bend 200 at the end of the first segment 199 that connects it to a second segment 201 which lies roughly parallel to the first segment 199. A third segment 202 attaches the second segment 201 to the fourth, and most distal, segment 203 of the staple leg. The fourth segment 203 has an arc-shaped curve whose center of rotation is approximately at the center of the U-shaped curve 200 between the first 199 and second 201 segments. The distal tip 204 of the fourth segment 203 is sharpened so that it easily penetrates the target vessel wall 150.

In the operation of this embodiment of the anastomosis staple, the staple legs 194 are initially in the position shown by solid lines 194 in Fig. 16. In this position the staple legs 194 are held well above the flange 205 on the distal end of the tubular body member, making it easier to insert the flange 205, with the everted graft vessel 192 attached, into the opening in the target vessel 150 and to seat the flange 205 against the inner surface of the target vessel 150. When the staple driver is advanced, the staple legs 194 initially rotate about attachment point 206 between the first segment and the tubular body member. After the staple leg 194 has rotated approximately 90 degrees, to the position shown by phantom lines 194', the first segment 199 comes into contact with the exterior of the tubular body member 198 and it stops rotating. Advancing the staple driver

further causes the second 201, third 202 and fourth 203 segments of the staple leg 194 to rotate around the U-shaped curve 200 connecting the first 199 and second 201 segments. The U-shaped curve 200 opens up to about 90 degrees as the curved fourth segment 203 of the staple leg 194 penetrates the target vessel wall 150, attaching the graft vessel 148 to the target vessel 150 to complete the anastomosis.

Another embodiment of the two-piece anastomosis staple is shown in Figs. 17A-17D. This embodiment differs somewhat in its construction from the embodiment of Fig. 1 although the operational principles are basically the same. The anastomosis staple 207 again includes an anchor member 208 and a coupling member 209 which interconnect. The anchor member 208 is made with a ring-shaped frame 210 which is pierced by two parallel rows of slots 211, 212. The metal 213 between the slots 211, 212 is deformed outward slightly to allow insertion of wire attachment legs 214. After the attachment legs 214 are inserted, the metal 213 is pressed inward to firmly attach the wire attachment legs 214 to the frame 210. Either before or after attachment to the ring-shaped frame 210, the wire attachment legs 214 can be formed with a desired curve, such as one of the curves described in Figs. 8A-8G. The distal tips 215 of the wire attachment legs are sharpened so that they easily penetrate the target vessel wall 150. The use of round wire attachment legs 214 with conically sharpened points 215, as opposed to the flat attachment legs 105 with chisel-shaped points 212 of Fig. 1, has shown some advantage in preliminary testing, in that the round wire legs 214 cause less trauma to the tissue of the target vessel wall 150 as they penetrate it. This may be due to the tendency of the conically sharpened tips 215 of the attachment legs 214 to dilate the tissue as they pass through the target vessel wall 150 more than to cut it. The tissue of the target vessel wall 150 is thus left more intact and may be less prone to dissections or other structural failure.

A plurality of retaining clips 216 are integrally formed on the proximal edge of the ring-shaped frame 210. The

retaining clips 216 perform the function of coupling the anchor member to the coupling member, similar to the interior surface features 117 of the anchor member 101 of Fig. 1. The coupling member 209, shown in Fig. 17B, has a tubular body 217 with a plurality of graft holding points 218 extending from its distal edge. If desired, the graft holding points 218 could be relocated, replaced with other gripping features, or eliminated entirely to avoid piercing the graft vessel 148 at the point of eversion. The graft holding points 218 perform one of the functions of the exterior surface features 116 of the coupling device 102 shown in Fig. 1 in that they attach the graft vessel 148 to the coupling member 209.

This embodiment of the two-piece anastomosis staple 207 can be applied with a slightly modified version of the anastomosis stapling tool 118 of Figs. 2, 6 and 7, following the sequence of steps of Figs. 5A-5G. The inner tube 124 of the stapling mechanism 119 grasps the anchor member 208 by either the ring-shaped frame 210 or the first segment of the attachment legs with the L-shaped legs of the staple retainer. After a small incision 151 has been made in the target vessel wall 150 at the desired anastomosis site, the stapling mechanism 119, with the vessel punch mechanism 120 inserted into the inner lumen 128, is positioned at the anastomosis site. The anvil 136 of the vessel punch 120 is inserted through the incision 151 and drawn back slightly to support the target vessel wall 150 so that the wire attachment legs 214 can be driven into the wall 150. The wire attachment legs 214 are then deformed by the stapling mechanism 119 to attach the anchor member 208 to the target vessel wall 150. The vessel punch 120 is then actuated to form a hole 152 through the target vessel wall 150 centered within the ring-shaped frame 210, as described in relation to Fig. 5D. The anchor member 208 is now attached to the target vessel wall 150 with the ring shaped frame 210 centered around the opening in the vessel wall 152, as shown in Fig. 17B. In this illustrative embodiment, the wire attachment legs 214 are configured so as to only partially penetrate the target vessel wall 150 so that they are embedded within the target vessel wall 150 in their

final, deployed configuration. This variation of the method may be preferred for attachment to some types of body tissues as the target vessel 150. The wire attachment legs 214 may also be pierced through the entire target vessel wall 150 before they are deformed so that they reside against the interior of the target vessel wall 150, as shown in Fig. 5C.

Once the anchor member 208 is attached to the target vessel 150, the vessel punch mechanism 120 is withdrawn and the graft insertion tool 121 with the graft vessel 192 everted over the distal end of the coupling member 209 is inserted into the inner lumen 128 of the stapling mechanism 119. The graft insertion tool 121 is used to press the coupling member 209 into the ring-shaped frame 210 of the anchor member 208 until the everted end 192 of the graft vessel 148 is firmly sealed against the outer surface of the target vessel wall 150 and the retaining clips 216 have seated over the proximal end of the coupling member 209. The coupling member 209 is held in the ring-shaped frame 210 by the retaining clips 216. The graft holding points 218 may be made so that they penetrate through the graft vessel wall 192 and into the target vessel wall 150, as shown in Fig. 17C, to increase the security of the anastomosis attachment. It should be noted that other sequences of operations are also possible for this embodiment, such as punching the opening in the target vessel wall prior to attachment of the anchor member.

Another embodiment of the two-piece anastomosis staple device 219 is shown in Figs. 18A-18F. This embodiment of the device lends itself to different manufacturing methods than the previously described embodiments. The anchor member 220 shown in perspective in Fig. 18A can be formed from a single piece of sheet metal by a combination of punching and drawing steps. The anchor member 220 has a plate 221 which is curved to fit the contours of the exterior surface of the target vessel wall 150, as seen in the end view Fig. 18B. For performing an aortic anastomosis, the radius of curvature of the plate 221 would typically be between 10 and 20 mm in an adult human. The plate 221 would be approximately 10 to 20 mm in width and 10 to 25 mm in length. The plate 221 is punched

so as to form integral attachment legs 222. This illustrative embodiment is shown with four integrally formed attachment legs 222, as best seen in top view Fig. 18C. A tubular proximal extension 223 is formed on the curved plate 221 by drawing the sheet metal plate 221 to form a cylindrical extension 223, then piercing or drilling it to open the proximal end of the cylinder. A final forming or stamping operation forms a radiused flange 224 at the proximal end of the tubular extension 223 that serves as a strain relief to prevent sharp bends or kinking of the graft vessel 148 close to the anastomosis site.

This embodiment of the anchor member can be attached to the target vessel wall by a sequence of operations similar to that described in relation to Figs. 5A-5G. Alternatively, the sequence of operations can be re-ordered so that the target vessel is punched before placement of the anchor member similar to that described for the one-piece embodiment of Fig. 9. Thus, either of the anastomosis stapling mechanisms 118, 179 previously described could easily be adapted to hold the anchor member 208 of Fig. 18 and to drive the attachment legs 222 into the target vessel wall 150.

The coupling member 225 in this embodiment is a toroidal ring 225 made of a resilient biocompatible material such as plastic, rubber or a springy metal having an outside diameter slightly smaller than the inside diameter of the cylindrical extension 223. The coupling member 225 is shown in Fig. 18D. The graft vessel 148 is prepared for anastomosis by passing the end of the vessel through the central opening of the toroidal ring 225 and everting it back 192 over the ring, as shown in the Fig. 18E. The ring 225, with the graft vessel 192 everted over it, is then collapsed or folded enough so that it can be inserted into the proximal tubular extension 223 of the anchor member 220. Once through the cylindrical extension 223, the toroidal ring 225 recoils to its expanded size, sealing the graft vessel wall 192 against the wall of the target vessel 150 and preventing the end of the graft vessel 192 from pulling out of the tubular extension 223. Alternatively, a cylindrical ring-shaped coupling member with

locking features, similar to those shown in Figs. 1 and 17B, can be used in conjunction with the anchor member of Fig. 18A.

Figs. 19A and 19B show an alternate construction 226 of the two-piece anastomosis staple 219 device of Figs.

5 18A-18E. In this variation of the device, the anchor member 227 may be made from a flat piece of sheet metal that is punched to form a flange 238 with a central aperture 228 and integrally formed attachment legs 229. The anchor member 227 is attached to the target vessel 150 with the central aperture  
10 aligned 228 with a preformed hole 152 in the wall of the target vessel 150. Alternatively, the anchor member 227 can be placed before the hole 152 is punched. The attachment legs 229 are shaped with straight distal segments, as shown by the phantom lines 231', that penetrate the target vessel wall 150  
15 in a linear fashion. A stapling device with a staple deforming anvil is passed through the hole 152 in the target vessel wall 150 to deform the attachment legs 229 so that they grip the target vessel wall 150, as shown by the solid lines 231. The attachment legs 229 can be deformed one at a  
20 time or some or all of the attachment legs 229 can be deformed at once depending on the design of the stapling device. Alternatively, the attachment legs 229 can be precurved and driven into the target vessel wall 150 from the outside.

The central aperture 228 in the flange 230 of the  
25 anchor member 227 has attachment features that interlock with matching attachment features on a first tubular coupling member 232. As an illustration of one possible configuration, the first coupling member is shown with two pairs of tabs 233, 234 extending radially from the distal edge of the first  
30 tubular coupling member 232. One pair of tabs 234 is slightly more distal than the other pair 233. The central aperture 228 of the anchor member 227 has a matching pair of slots 235 extending from the aperture 228. The first coupling member  
35 232 is joined to the anchor member 227 by aligning the more distal pair of tabs 234 with the slots 235, pushing the tabs 234 through the slots 235, then turning the coupling member 232 until the tabs 234 are locked onto the edges of the aperture 228. The first tubular coupling member 232 may be

made with integrally formed graft holding points 236 which are cut and bent inward from the wall of the first tubular coupling member 232 to hold the everted graft in place. The graft may be everted over a second tubular coupling member 196, which is inserted into the first tubular coupling member 232 and is attachable to the first tubular coupling member at the proximal ends of the tubular coupling members, as shown in Fig. 19B.

Fig. 20 shows a fourth alternate construction 237 of the two-piece embodiment of the anastomosis staple device 100 of Fig. 1. The anchor member 238 of the anastomosis staple device 237 may be formed from a piece of sheet metal, similarly to the other alternate embodiments previously described. The anchor member 238 has a distal plate 239 which may be flat or curved to match the exterior curvature of the target vessel 150. Multiple attachment legs 240 are cut from the plate material 239, sharpened at the ends 241, and bent with a first section 242 that angles upwardly from the plate 239 and a second section 243 that is angled downward to pierce the target artery wall, as shown in phantom lines 243' in Fig. 20. Preferably, the second section 243 is curved with a radius of curvature approximately equal to the length of the first section 242. A tubular proximal extension 244 with a slight hourglass shape extends from the distal plate 239 of the anchor member 238.

The coupling member 245 of the anastomosis staple device 237, shown in Fig. 20, is made in a tubular shape of a biocompatible resilient material such as plastic, rubber or a springy metal, such as a nickel-titanium alloy. The tubular coupling member 245 has a slight hourglass shape in axial cross section, matching the interior shape of the tubular proximal extension 244 of the anchor member 238. If desired, the tubular coupling member 245 can be made with slightly thickened proximal 246 and distal 247 extremities which act as O-rings molded integrally with the wall of the tube. The tubular coupling member 245 can be made with a continuous tubular wall or with a longitudinal slot in the wall of the tube to increase the resiliency of the coupling member.

Alternatively, the tubular coupling member 245 can be made of a coiled spring with an hourglass shape in axial cross section.

As with the previously described embodiments, the anchor member 238 can be applied to the exterior of the target vessel 150 either before or after an opening 152 has been created with a vessel punch. To place the anchor member 238, the plate 239 of the anchor member 238 is pressed against the exterior surface of the target vessel 150 at the anastomosis site and the attachment legs 240 are pressed to drive the sharpened tips 241 through the target vessel wall 150. If an opening 152 has not yet been made in the target vessel wall 150, a vessel punch is inserted through the lumen 244 of the proximal tubular extension 244 to create an opening 152 in the wall 150 concentric with the tubular extension 244.

Meanwhile, the graft vessel 148 is prepared by placing it through the lumen of the tubular coupling member and everting the end 192 of the graft vessel 148 over the outside of the coupling member 245. To complete the anastomosis, the coupling member 245 with the end 192 of the graft vessel 148 attached is collapsed or folded and inserted into the proximal tubular extension 244 of the anchor member 238. The resilience of the coupling member 245, combined with the matching hourglass shapes of the two parts of the staple device, locks the parts together to form a leak-proof anastomosis.

The coupling member 245 can be dimensioned so that the distal end of the coupling member 245 extends through the opening 152 in the target vessel wall and the everted edge 192 of the graft vessel 148 seals within the opening 152, as illustrated, or against the interior surface of the target vessel 150 similarly to the one-piece embodiment of the anastomosis staple device illustrated in Fig. 9.

Alternatively, the coupling member 245 can be shaped so that it presses the everted edge 192 of the graft vessel 148 against the exterior surface of the target vessel 150 to create a leak-proof seal similar to the embodiment of Fig. 1.

In a further aspect of the invention, an anastomosis fitting is provided for rapidly and reliably creating an end-to-side anastomosis between a graft vessel and a target vessel. A first representative embodiment of an anastomotic fitting 250 according to this second aspect of the present invention is shown in Figs. 21A-21C. The anastomotic fitting 250 is made up of two coacting parts: a) a tubular inner sleeve 251 which has an internal lumen 252 of sufficient size to accommodate the external diameter of the graft vessel 254 and an inner flange 253 which is attached or formed at the distal end of the sleeve 251 so as to be positioned within the lumen 256 of the target vessel 255, and b) an outer flange 260 which has a central orifice 261 that is sized to fit over the exterior of the inner sleeve 251 to be positioned against the exterior surface 258 of the target vessel wall 255. The anastomotic fitting 250 is thus held in place by compressing the target vessel wall 255 between the inner 253 and outer 260 flanges. An adjustable locking mechanism 262 holds the outer flange 260 on the inner sleeve 251 at a selected position to create a tailored degree of tissue compression at the anastomotic site. The anastomosis fitting 250 can be made of various biocompatible materials, such as stainless steel, titanium alloys, plastic, pyrolytic carbon, etc. Additionally, biocompatible coatings could be applied to the inner and/or outer surfaces of the fitting 250 to increase its acceptance by the body tissues or to reduce thrombosis.

The inner sleeve 251 is a tubular member with an internal lumen 252 large enough to accommodate the external diameter of the graft vessel 254, either a natural graft vessel or an artificial graft vessel. Natural saphenous vein autografts typically have an internal diameter between 3 mm and 10 mm and an external diameter between 4 mm and 11 mm. Pedicled arterial grafts, such as the internal mammary artery or the gastroepiploic artery typically have an internal diameter between 2 mm and 7 mm and an external diameter between 3 mm and 8 mm, with thicker, more muscular walls. Artificial prosthetic graft vessels, made of materials such as Dacron or Goretex, typically have a diameter of 3 mm to 30 mm.

The tubular inner sleeve 251 should be made of a rigid biocompatible material, such as stainless steel, titanium alloys or a rigid biocompatible plastic. The wall thickness of the sleeve is preferably about 0.2 mm to 2.0 mm.

5           The distal end of the inner sleeve is flared at an angle of approximately 45 to 75 degrees to form a conical inner flange 253. The inner flange 253 has an outer diameter of approximately 1.3 to 2.5 times the inner diameter of the inner sleeve 251. The use of a conical or rounded inner  
10 flange 253 helps to improve the hemodynamic efficiency of the anastomosis connection by improving the orifice coefficient at the entrance to the graft vessel 254. It also assures that the finished anastomosis will not protrude into the lumen 246 of the target vessel 255 or upset the hemodynamic flow in that  
15 vessel. The exterior of the tubular inner sleeve 251 has a series of circumferential ridges 263 or threads which may be sawtooth in shape.

          The outer flange 260 has a central orifice 261 which is sized to fit over the exterior of the tubular inner sleeve  
20 251. The outer flange 260 has an outer diameter of approximately 1.3 to 3.0 times the inner diameter of the inner sleeve 251. A ratchet mechanism 264 within or adjacent to the central orifice 261 of the outer flange 260 engages the circumferential ridges 263 on the exterior of the tubular  
25 inner sleeve 251. The ratchet 264 can be strictly a one-way mechanism so that the outer flange 260 can only move in the direction of the inner flange 253 or a release mechanism can be incorporated so that the outer flange 260 can be moved away from the inner flange 253 in case of premature activation of  
30 the ratchet mechanism 264. Alternatively, the outer flange 260 could be threaded to the exterior of the tubular inner sleeve 251. The distal edge 265 of the outer flange 260 may incorporate a plurality of attachment spikes 266 that engage and hold the wall of the target vessel 255 and/or the everted  
35 wall 259 of the graft vessel 254 when the outer flange 260 is applied. In the preferred embodiment which is intended for creating an anastomosis between a coronary artery bypass graft and the ascending aorta, the outer flange 260 has 4 to 12

spikes of 1 to 3 mm length and 0.2 to 0.5 mm diameter. Variations of this configuration may be made where appropriate for different graft vessels and target vessels.

The anastomosis is performed by passing the end 259 of the graft vessel 254 through the inner lumen 252 of the tubular inner sleeve 252 until the end of the vessel extends a short distance from the distal end of the sleeve, as shown by phantom lines 259' in Fig. 21A. The end 259 of the graft vessel 254 is then everted over the conical inner flange 253 of the fitting 250 to form an atraumatic attachment, as shown in Fig. 23A. If desired, a loop of suture can be tied around the everted end 259 of the graft vessel 254 to hold it in place on the inner flange 253 and/or the tubular inner sleeve 251. The conical inner flange 253 and the everted end 259 of the graft vessel 254 are then passed through an opening 267 that has previously been made in the wall of the target vessel 255 with an instrument such as a vessel punch, as shown in Fig. 21B. The diameter of the opening 267 in the target vessel wall is preferably about the same as the external diameter of the tubular inner sleeve 251. The opening 267 may need to stretch slightly to allow the conical inner flange 253 to pass through. The elastic recovery of the target vessel wall 255 around the opening 267 helps to create an anastomotic seal by contracting around the inner sleeve 251 and the everted graft vessel wall 259. The outer flange 260 is then slid onto the proximal end of the inner sleeve 251. If the anastomosis being performed is the first anastomosis of a free graft, such as a saphenous vein graft, with the other end of the graft unattached, then the outer flange 260 can be slid over the graft vessel 254 from the free end. If the other end of the graft vessel 254 is not free, such as when performing a second anastomosis or a distal anastomosis on a pedicled graft like the IMA, then the outer flange 260 should be back loaded onto the graft vessel 254 or preloaded onto the proximal end of the inner sleeve 251 before the end 259 of the graft vessel 254 is attached to the inner flange 253 of the fitting 250. The outer flange 260 is slid down the inner sleeve 251 until it contacts the exterior wall 258 of the target vessel 255 and

a desired degree of compression of the target vessel wall 255 is applied between the inner 253 and outer 260 flanges. The ratchet mechanism 264 of the outer flange 260 locks the flange 260 in place on the tubular inner sleeve 251 to complete the anastomosis, as shown in Fig. 21C.

Figs. 22A-22D show an anastomosis fitting 268 which is a variation of the embodiment of Figs. 21A-21C. In this variant the inner flange 269 has a flat annular configuration, rather than a conical shape as in the previously described embodiment. To insure that the completed anastomosis does not protrude into the blood flow lumen 256 of the target vessel 255, the outer flange 270 of the fitting is concave on its distal surface 271. The central orifice 272 of the outer flange 270 tapers proximally to a locking ring 273 within the central orifice 272 that slips over and locks with a collar 274 on the proximal end of the tubular inner sleeve 275. As shown in Fig. 22C, when the outer flange 270 is applied to the exterior surface 258 of the target vessel 255 and locked onto the collar 274 of the tubular inner sleeve 275, the inner flange 269 is drawn into the concave outer flange 270, so that the anastomosis is flush with or recessed into the inner wall 257 of the target vessel 255. This helps to assure a hemodynamically correct inflow at the entrance to the graft vessel 254. Two or more collars 274 may be provided on the tubular inner sleeve 275 to allow adjustable compression by the anastomotic fitting 268.

Figs. 23A-23D show another variant 276 of the embodiment of the anastomosis fitting of Figs. 21A-21C and Figs. 22A-22D. In this variant the concave outer flange 277 has a simple central orifice 278 without a locking ring. The locking mechanism is provided by multiple downwardly oriented tangs 279 or tapered ridges, which have been formed in the sidewall of the tubular inner sleeve 280 by cutting, punching or molding. The outer flange 277 is slid over the proximal end of the inner sleeve 280 and over the tangs 279, which engage the proximal end of the outer flange 277 to lock the outer flange 277 into place on the inner sleeve 280, as illustrate in Fig. 23C. If desired, multiple parallel rows of

tangs 279 can be provided at different axial locations on the inner sleeve 280 to accommodate different thicknesses of the target vessel wall 255 and to provide a tailored degree of tissue compression at the anastomosis site. Optionally, the underside of the outer flange 277 may have a plurality of attachment points which engage and hold the target vessel wall 255 near the opening 267 in it, adding security to the anastomosis attachment without piercing the target vessel wall 255.

Figs. 23A-23D also illustrate a variation of the method for applying the anastomosis fitting. In this embodiment, the method includes applying a suture 281 to the everted end 259 of the graft vessel 254 to secure it to the inner flange 282. As best seen in the top view Fig. 23D, the everted end 259 of the graft vessel 254 has been secured to the inner flange 282 of the fitting by making a running stitch around the end of the graft vessel with a suture 281 on the back of the inner flange 282 and tying it to create a purse string that holds the end 259 of the graft vessel 254 in place.

A second representative embodiment of an anastomotic fitting 283 employing inner 284 and outer 285 flanges has an expanding inner flange 284 which facilitates the atraumatic attachment of the graft vessel 254 to the fitting 283 and makes it easier to pass the inner flange 284 and the everted graft vessel 259 through the opening 267 in the target vessel wall 255. Two variations of such an expanding inner flange are shown in Figs. 24A-24D and Figs. 25A-25H. The graft vessel 254 is passed through an internal lumen 287 of an inner sleeve 286 which has the expandable inner flange 284 attached at its distal end. The end 259 of the graft vessel 254 is everted over the unexpanded inner flange 284'. The inner flange 284' and the everted end 259 of the graft vessel 254 are passed through the opening 267 in the target vessel wall 255. Once the inner flange 284' of the fitting 283 is in the lumen 256 of the target vessel 255, it is expanded to a diameter 284 which is significantly larger than the opening 267 in the target vessel wall 255. Then an outer flange 285

is applied and locked into a selected position on the inner sleeve 286 as described above to complete the anastomosis.

In the first variant of the expanding inner flange 284, shown in Figs. 24A-24D, the flange 284 and a portion of the inner sleeve 286 are slotted to create multiple fingers 288 which are initially collapsed inward toward the center of the inner sleeve 286. The ends of the fingers form sector-shaped sections 289 of the flange 284, as seen in the distal end view of Fig. 24D. When the flange 284 is collapsed inward 284', as in Fig. 24C, the sectors 289 fit together to form a smaller diameter flange 284' with a passage 287' through the center large enough for a collapsed graft vessel 254 to fit through. A tubular former 290 is slidably received within the slotted inner sleeve 286 and has an axial lumen 291 large enough to receive the graft vessel 254. The tubular former 290 initially resides in a proximal position, as shown in Fig. 24A. The tubular former 290 has a ridge 292 at its proximal end that positions the tubular former 290 in the correct location with respect to the inner sleeve 286 when the tubular former 290 is in its distal, deployed position. An outer flange 285, with a concave distal surface 293 may be permanently attached to the inner sleeve 286 proximal to the expanding inner flange 284. Alternatively, the outer flange 285 can be provided as a separate component which is attached to the inner sleeve 286 after the graft vessel 254 has been attached or at the end of the anastomosis procedure.

In operation, the graft vessel 254 is inserted through the axial lumen 291 of the tubular former 290 and through the internal lumen 287 of the slotted inner sleeve 286 and through the central opening 287' between the collapsed sectors 289' of the inner flange 284'. The end 259 of the graft vessel 254 is everted over the collapsed sectors 289' of the flange 284'. The collapsed flange 282' and the everted end 259 of the graft vessel 254 are inserted through the opening 267 in the target vessel 255. Then, the tubular former 290 is slid distally within the slotted inner sleeve 286. The tubular former 290 forces the fingers 288 outward, expanding the flange 284 within the target vessel 255. If the

outer flange 285 is already attached to the inner sleeve 286 at this point, the distal surface 283 of the outer flange 285 is pressed against the exterior surface 258 of the target vessel 255 as the expandable inner flange 284 is being  
5 deployed to complete the anastomosis. If, on the other hand, the outer flange 285 has been supplied as a separate component, the outer flange 285 is slipped over the proximal end of the inner sleeve 286 after the expandable inner flange 284 has been deployed and a desired degree of tissue  
10 compression is applied between the inner 284 and outer 285 flanges of the fitting 283 to complete the anastomosis, as shown in Fig. 24B.

A second variant of the anastomotic fitting 294 with an expanding inner flange 298 is shown in Figs. 25A-25H. The  
15 inner sleeve 295 of the fitting 294 is slotted along its entire length to form multiple fingers 296 that are oriented essentially longitudinally to the inner sleeve 295. A collar 297 on the proximal end of the slotted inner sleeve 295 joins the multiple fingers 296 together in a tubular configuration.  
20 A concave outer flange 299 is captured on the slotted inner sleeve 295 by the proximal collar 297. As seen in the end view in Fig. 25E, the inside diameter of the collar 297 has notches 301 which are extensions of the slots 300 between the fingers 296 of the inner sleeve 295. Each of the fingers 296  
25 has a bend 302 in it to predispose it to bend outward at the middle when contracted longitudinally. A tubular forming tool 303 for expanding the inner flange 298 is slidably received within the slotted inner sleeve 295. The distal end of the tubular forming tool 303 is crenellated with multiple radially  
30 extending tabs 304. The multiple radially extending tabs 304, as seen in the end view in Fig. 25F, are configured to fit through the notches 301 in the collar 297 and into the slots 301 of the inner sleeve. The tubular forming tool 303 is inserted into the slotted inner sleeve 295 by aligning the  
35 radially extending tabs 304 with the notches 301 in the collar 297 and sliding it distally along the slots 300 until the tabs 304 pass the distal ends 305 of the fingers 296. Then, the tubular forming tool 303 is rotated slightly so that the

radially extending tabs 304 engage the distal ends 305 of the fingers 296 of the slotted inner sleeve 295, as shown in Fig. 25A.

The anastomosis is performed by passing the graft vessel 254 through the internal lumen of the forming tool 303 within the slotted inner sleeve 295 and everting it 259 over the distal ends 305 of the fingers 296. A loop of suture 306 can be used to hold the everted vessel 259 in place. The fingers 296 of the fitting 294 and the everted end 259 of the graft vessel 254 are inserted through an opening 267 in the target vessel wall 255. When the tubular forming tool 303 is slid proximally with respect to the slotted inner sleeve 295, the radially extending tabs 304 of the tubular forming tool 303 bear against the distal ends 305 of the fingers 296 compressing them longitudinally. The fingers 296 bow outward, folding at the bend 302 to expand and create an inner flange 298 which engages the inner surface 257 of the target vessel wall 255. The tubular forming tool 303 is pulled further proximally until the newly formed inner flange is drawn into the concave outer flange 299, compressing the target vessel wall 255 and recessing the inner flange 298 and the anastomotic connection into the target vessel wall 255, as shown in Fig. 25D. The tubular forming tool 303 can now be removed by rotating it with respect to the slotted inner sleeve 295 so that the tabs align with the slots 300 and withdrawing it from the fitting 294. The mass of foreign material that is left as an implant at the anastomotic site is thus reduced.

Alternatively, the inner sleeves 295 and the tubular forming tool 303 can be formed integrally or welded together as one piece, in which case both the inner sleeve 295 and the tubular forming tool 303 would remain in the finished anastomosis. As a further alternative, the tubular forming tool 303 could be made to break away from the inner sleeve 295 when a certain force is applied.

In a further aspect of the invention, the anastomotic fitting has a single-piece construction with an inner sleeve that is integrally attached to a fixed inner

flange and to a deformable outer flange. Three variants of the anastomotic fitting with a deformable outer flange and their forming tools are shown in Figs. 26A-26I, 27A-27D and 28A-28I.

5           The first variant of the anastomotic fitting 306 with a deformable outer flange is shown in Figs. 26A-26I. The anastomotic fitting 306 has a tubular main body 307 having an internal lumen 303 sized to accommodate the external diameter of the graft vessel 254. A fixed inner flange 309 is attached  
10 to the distal end of the tubular body 307. On the proximal end of the tubular body 307 are a plurality of hingedly attached outer flange segments 310. In this illustrative embodiment, there are four such flange segments 310 which are enlarged at their outer edges to form sector-shaped segments  
15 310 of the outer flange 311. The hinge portion 312 of each flange segment 310 is a deformable strip of metal 312 connecting the flange segment 310 to the main tubular body 307. Preferably, the tubular body 307, the inner flange 309 and the flange segments 310 of the outer flange 311, including  
20 the deformable hinge portion 312, are integrally formed of a single piece of biocompatible metal, such as stainless steel, a titanium alloy or a cobalt alloy (e.g. Carpenter MP35).

          The distal end of a device 313 for applying the anastomosis fitting is shown in Fig. 26B. The device has an  
25 inner tubular member known as the anvil 314 and an outer tubular member called the driver 315. The distal end of the anvil 314 has a gripper 316 for holding onto the anastomosis fitting 306. The gripper 316 in the preferred embodiment has a bayonet-type fitting with four L-shaped gripping fingers 317  
30 which hold the fitting 306 by hooking onto each of the flange segments 310 at the deformable hinge portion 312. The driver slides 315 telescopically over the outside of the anvil 314 and has an annular driving surface 318 on its distal end configured to engage the outer ends of each flange segment  
35 310. The anvil 314 and the driver 315 can be made in a long version, approximately 15 to 30 cm in length, for performing port-access CABG surgery or a short version, approximately 10

to 20 cm in length, for performing standard open-chest CABG surgery.

The fitting 306 is prepared for performing the anastomosis by attaching the fitting 306 to the gripper 316 on the distal end of the anvil 314. Then, the graft vessel 254 is passed through the inner lumen 319 of the anvil 314 until the end 259 to be anastomosed extends a short distance from the distal end of the fitting 306. The end of the graft vessel 259 is everted over the inner flange 309 of the fitting to form an atraumatic attachment between the two. If the anastomosis being performed is part of a port-access CABG surgery procedure, the fitting on the end of the application tool is inserted into the patient's chest through an access port made through one of the intercostal spaces. The inner flange 309 and the everted end 259 of the graft vessel 254 are inserted through an opening 267 that has been made in the wall of the target vessel 255. The fitting 306 is pulled back slightly so that the inner flange 309 is flush against the interior surface 257 of the target vessel. Then, the driver 315 is pushed distally with respect to the anvil 314 until the driving surface 318 deforms the outer flange segments 310 against the exterior surface 258 of the target vessel wall 255 and the desired degree of compression of the vessel wall 255 is obtained. The anvil 314 is rotated slightly to release the gripper 316 from the flange segments 310 of the fitting 306 and the application device 313 is withdrawn from the patient's body.

The second variant of the anastomotic fitting 320 with a deformable outer flange 321 is shown in Figs. 27A-27D. This variant is largely the same as the first variant just described in connection with Figs. 26A-26I with the exception of the inner flange 322 construction. In this embodiment, the inner flange 322 is slightly conical in order to provide a more hemodynamically efficient inlet to the graft vessel 254 at the anastomosis. In addition, a plurality of attachment spikes 323 preferably 6 to 8 spikes, have been provided along the periphery of the inner flange 322. In a preferred configuration, the anastomotic fitting 320 is fully deployed,

the spikes 323 penetrate through the everted wall 259 of the graft vessel 254 and into the wall of the target vessel 255 to create a more secure attachment for the anastomosis. When the outer flange segments 324 are deformed against the exterior surface 258 of the target vessel 255 and compress the vessel wall 255 such that they engage the spikes 323 on the inner flange 322 for a very secure attachment.

The third variant of the anastomotic fitting 325 with a deformable outer flange 326 is shown in Figs. 28A-28I. The anastomotic fitting 325 has a tubular main body 327 with an internal lumen 328 sized to accommodate the external diameter of the graft vessel 254. The walls of the tubular body 327 have a pair of L-shaped slots 329 that are open at the top of the tubular body 327 to form a bayonet fitting. An inner flange 330, which may be slightly conical in shape, is attached to the distal end of the tubular body 327. Attached to the proximal end of the tubular body 327 is a deformable outer flange 326, comprising a multiplicity of axially-oriented bars 331 separated by axial slots. 332 The axially-oriented bars 331 are attached at their distal ends to the tubular main body 327, and are joined at their proximal ends by a ring 333 forming the proximal end of the fitting 325. The bars 331 are bent outwardly near their centers 334 so that the bars 331 preferentially bend outwardly when compressed. The tubular body 327, the inner flange 330 and the deformable outer flange 326 are preferably machined of a single piece of biocompatible metal, such as stainless steel, a titanium alloy or a cobalt alloy. The geometry of this device could also be configured so that the bars 331 of the outer flange 326 start off almost straight, and are deformed further to reach their final geometry.

A device 335 or applying the anastomotic fitting is shown in Fig. 28D-F. The device 335 has an inner tubular member 336 which has a pair of radially extending tabs 337 on its distal end that interlock within the L-shaped slots 329 in the tubular body 327 of the fitting 325. An outer tubular member 338, the pusher 338, slides telescopically over the outside of the inner tubular member 336 and has an annular

driving surface 339 on its distal end. This anastomosis fitting application device 335 can be made in a long version for port-access CABG surgery or a short version for standard open-chest CABG surgery.

5           The fitting 325 is prepared for performing the anastomosis by attaching the anastomotic fitting 325 to the inner tubular member 336. Then, the graft vessel 154 is passed through the inner lumen 340 of the inner tubular member 336 until the end 159 to be anastomosed extends a short  
10 distance from the distal end of the fitting 325. The end 159 of the graft vessel 154 is everted over the inner flange 330 of the fitting 325 to form an atraumatic attachment, as shown in Fig. 28D. If the anastomosis being performed is part of a port-access CABG surgery procedure, the fitting 325 on the end  
15 of the application tool 335 is inserted into the patient's chest through an access port made through one of the intercostal spaces. The inner flange 330 and the everted end 159 of the graft vessel 154 are inserted through an opening 267 that has been made in the wall of the target vessel 225,  
20 as shown in Fig. 28E. The fitting 325 is pulled back slightly so that the inner flange 330 is flush against the interior surface 257 of the target vessel 255. Then, the pusher 338 is moved distally with respect to the inner tubular member 336 until the driving surface 339 contacts the proximal surface of  
25 the deformable outer flange 326. The pusher 338 deforms the outer flange 326 by compressing the bars 331, which bend outwardly and fold into a flattened configuration, as shown in Fig. 28F, to form a radially spoked outer flange 326'. The pusher 338 further deforms the bars 331 to press the outer  
30 flange 326' against the exterior surface 258 of the target vessel wall 255 and obtain the desired degree of compression between the inner 330 and outer 326' flanges. The inner tubular member 336 is removed by rotating it with respect to the fitting 325 and withdrawing the tabs from the L-shaped  
35 slots 329.

A further embodiment of an anastomosis fitting 340 according to the invention is illustrated in Fig. 29A-C. The anastomosis fitting of Fig. 29A-C may be particularly

advantageous with older patients, diabetic patients and other patients whose veins are no longer as resilient as they once were, where it may be difficult to stretch the saphenous vein graft enough to evert it over a large inner flange. This is also true of many artificial graft materials that will not stretch at all to evert them over a large flange. The anastomosis fitting 340 of Fig. 29 A-C has a tubular body member 341 with a small primary inner flange 342 attached to the distal end. Threads 343 or similar features on the inner surface the proximal end of the tubular body member 341 facilitate grasping the tubular body member 341 with an application instrument. A secondary inner flange washer 344 has a central orifice 345 with inwardly facing tabs 346 configured to engage the primary inner flange 342, as seen in distal end view 29C. An outer flange 347 is configured to slide over the proximal end of the tubular body 341 and is locked in place by a self-locking retaining washer 348 with upwardly inclined tabs 349 that frictionally engage the outer surface of the tubular body 341, allowing the outer flange 347 to slide in the distal direction with respect to the tubular outer body 341, but not in the proximal direction. The outer flange 341 may have a plurality of attachment spikes 350 on its distal surface to penetrate the outer wall 258 of the target vessel 255.

In operation, first the outer flange 347 with its retaining washer 348 and then the secondary inner flange washer 344 are back loaded onto the holder 352 of the application device 351. Next, the tubular body 341 is threaded onto the distal end of the holder 352. The graft vessel 254 is passed through the internal lumen 353 of the application instrument 351 and the distal end 259 of the graft vessel 254 is everted over the small primary inner flange 342 of the anastomosis fitting 340. The secondary inner flange washer 344 is then slid distally so that it bears against the proximal face of the inner flange 342, as shown in Fig. 29A. The primary inner flange 342, with the everted graft vessel 259 attached, and the secondary inner flange washer 344 are inserted through an opening 267 that has been made in the

target vessel wall 255 as shown in Fig. 29A. A slight tension is exerted on the application instrument 351 to seat the primary inner flange 342 and the secondary inner flange washer 344 against the interior surface 257 of the target vessel wall 255 and the driver 354 is advanced distally to press the outer flange 347, with its self-locking retaining washer 348, onto the exterior of the tubular body member 341 until the desired degree of compression between the inner 242, 344 and outer flanges is obtained. The holder 352 is disengaged from the tubular body member 341 and the entire application instrument 351 is withdrawn from the body.

A distal end view of the completed anastomosis is shown in Fig. 29C. The larger diameter of the secondary inner flange washer 344 adds to the security of the anastomosis attachment, while it does not require the graft vessel 254 to be stretched to fit over a large inner flange. Only a very small amount of foreign material is exposed within the target vessel lumen and it is spaced a short distance from the actual anastomosis site which may reduce the likelihood of complications. Because the secondary inner flange 344 washer only contacts the primary inner flange 342 and the everted graft vessel wall 259 at four small points, it will not interfere with the intima-to-intima approximation of the graft vessel 259 and the target vessel 255 which is preferred in order to promote endothelialization of the anastomosis site.

Figs. 30A-30F illustrate an embodiment of the anastomosis fitting 355 of the present invention which combines an inner tubular member 356 having deformable attachment legs 357 at its distal end, with an outer flange 358. The deformable attachment legs 357 have an initial position 357 allowing the graft vessel 254 to be easily everted over and penetrated by the attachment legs 357. The attachment legs 357 are subsequently deformed to a deployed position 357' wherein the attachment legs 357' perform the function of the inner flange in many of the above-described embodiments by engaging the interior surface 257 of the target vessel 255 and compressing the tissue between the attachment legs 357' and the outer flange. 358 The inner tubular member

356 is shown in Fig. 30A. The tubular member 356 is preferably made from a biocompatible metal, such as an alloy of stainless steel, titanium or cobalt. The tubular member 356 has an internal lumen 359 of sufficient size to accommodate the external diameter of the graft vessel 254. The tubular member 356 is made with a plurality of attachment legs 357 extending axially from its distal end 360. This illustrative embodiment is shown with four attachment legs 357. Other exemplary embodiments may have from three to twelve attachment legs 357 depending on the sizes of the graft vessel 254 and target vessel 255 to be joined. The attachment legs 357 preferably have a width of approximately 0.5-2.0 mm, more preferably about 1.0 mm, and a thickness of approximately 0.1-0.5 mm, more preferably about 0.25 mm. The width and thickness of the attachment legs 357 is chosen so that the legs 357 will be relatively rigid when they are in their deployed position 357', yet they are still easily deformed using the special forming dies 369, 370, 371 provided with the anastomosis system. The distal ends 361 of the attachment legs 357 are sharpened to easily penetrate the walls of the graft vessel 254 and target vessel 255. The exterior surface of the tubular member 256 may be made with a groove or slot 362 around its circumference as a detent for the outer flange 358 spaced a calculated distance from the distal end 360 of the tubular member 356 to provide a desired degree of compression on the anastomosis when the outer flange 358 locks into the groove. 362 A plurality of holes 363 through the wall of the tubular member 356 (three holes 363 in this illustrative embodiment) are located near the proximal end of the tubular member 356 to facilitate grasping the device 355 with an application instrument 372.

The outer flange 358, illustrated in Fig. 30B, has a central orifice 364 which is sized to fit over the exterior of the tubular member 356. The outer flange 358 has a locking mechanism, which includes a self-locking retaining washer 365 with upwardly inclined locking tabs 366 integrally formed with the outer flange, 358 to slidably position the outer flange 358 on the exterior surface of the tubular member 356.

Alternatively, the self-locking retaining washer 365 can be manufactured separately and attached to the outer flange 358. The upwardly inclined locking tabs 366 allow the retaining washer 365 to slide in the distal direction over the exterior of the tubular member 356, but resist sliding in the proximal direction. When the upwardly inclined locking tabs 366 lock into the groove 362 in the exterior surface of the tubular body 356 it forms a more permanent attachment, strongly resisting movement in the proximal direction. Other locking mechanisms can also be used for positioning the outer flange 358 with respect to the tubular member 356, such as ratchet mechanisms, detents, or releasable locking devices. The distal surface 367 of the outer flange 358 is configured to contact the exterior surface 258 of the target vessel 255. Preferably, the distal surface 367 of the outer flange 358 is slightly concave, as illustrated. If desired, the outer flange 358 may be made with short spikes extending from its distal surface. The outer periphery of the outer flange 358 is perforated with a series of holes 368, which are positioned to be aligned with the distal ends 361' of the attachment legs 357' of the tubular member 356 when the fitting 355 is fully deployed. Making the holes 368 in a multiple of the number of attachment legs 357, as in the present example which has eight holes 368, corresponding with four attachment legs 357, facilitates aligning the holes 368 with the distal ends 361' of the attachment legs 357'. The outer flange 358 is preferably made from a biocompatible metal, such as an alloy of stainless steel, titanium or cobalt or a biocompatible polymer. Alternatively, a separate locking washer 365 made from a biocompatible metal can be joined to an outer flange 358 made of a polymer or other biocompatible material.

The anastomosis fitting 355 is part of a complete anastomosis system for forming and applying the anastomosis fitting 355 to create an end-to-side anastomosis. A set of three forming dies 369, 370, 371 are configured to deform the attachment legs 357 of the anastomosis fitting 355 from their initial position 357 to a deployed position 357', and a specialized grasping tool 372 is used to insert the deployed

inner tubular member 356 through an opening 267 in the side wall of the target vessel 355. These tools, which will be described in more detail in the operational description below, facilitate the rapid and repeatable deployment of the anastomosis fitting 355 with a minimum of manual manipulation required.

In operation, the end-to-side anastomosis procedure is performed using the anastomosis fitting 355 by first preparing the free end 259 of the graft vessel 254 for attachment. If the anastomosis being performed is a second anastomosis or is being performed on the free end of a pedicled graft, the outer flange 358 must first be backloaded onto the graft vessel 254 with the distal surface 367 facing the end 259 of the vessel to be attached. If the anastomosis is being performed as the first anastomosis on a free graft, the outer flange 358 can be backloaded onto the graft vessel 254 at this time or it can be passed over graft vessel 254 from the far end at a later point in the procedure, whichever is preferable. Next, the free end 259 of the graft vessel 254 is passed through the internal lumen 359 of the inner tubular member 356 so that it extends a short distance from the distal end 360 of the tubular member 356, as shown in Fig. 30C. The free end 259 of the graft vessel 254 is everted and the attachment legs 357 are pierced through the everted wall 259 of the graft vessel 254 to prepare the graft vessel 254 as shown in Fig. 30D. If desired, a loop of suture can be tied around the everted end 259 of the graft vessel 254 to help secure the graft vessel 254 in its everted position over the exterior surface of the tubular member 356.

After piercing the graft vessel wall 259, the attachment legs 357 of the tubular member 356 are deformed from their axially extending position 357 by first bending them outward so that they extend radially from the distal end 360 of the tubular member 356, then bending the distal ends 361' of each of the attachment legs 357' so that they are directed proximally with respect to the tubular member 356, as shown in Fig. 30E. For a typical application of the anastomosis fitting 355 in making an end-to-side anastomosis

between a saphenous vein graft and the ascending aorta, the radially extending portion 373 of each deployed attachment leg 357' is about 3-4 mm long, and the proximally directed distal portion 374 of each deployed attachment leg 357' is about 2-5 mm long. These dimensions will vary somewhat depending on the size and the wall thickness of the graft vessel and the target vessel to be joined.

A set of three forming dies 369, 370, 371 are provided for rapidly and repeatably forming the anastomosis fitting 355 into the deployed position shown in Fig. 30E. The first die 369 is cylindrical in shape with a counterbored recess 375 on one end which is sized to hold the proximal end of the tubular member 356 of the anastomosis fitting. An annular forming surface 376 on the end of the die 369 surrounds the counterbored recess 375. An annular space 377 between the counterbored recess 375 and the annular forming surface 376 provides sufficient clearance for the everted end 259 of the graft vessel 254 when the inner tubular member 356 of the anastomosis fitting 355 is inserted into the counterbored recess 375. The proximal end of the graft vessel 354 extends through a central lumen 378 in the first die 369 and exits the die through a notch 379 in the far end of the die 369 which communicates with the lumen 378. The second die 370 has a conically tapered end 380 which is used to initiate the outward bend of the attachment legs 357 by pressing the tapered end 380 between the attachment legs 357, as shown in Fig. 30G. The third die 371 is cylindrical in shape with a counterbore 381 on one end that is sized to fit over the outside of the first die 369 with a radial clearance sufficient for the thickness of the attachment legs 357'. There is a forming shoulder 382 within the counterbore 381 of the third die 371, and there is a tapered edge 383 leading into the counterbore 381. The third die 371 is placed over the distal end of the inner tubular member 356 after the attachment legs 357 have been bent outward by the second die 370. As the counterbore 381 of the third die 371 slides over the exterior of the first die, 369 the radially extending portion 373 of the attachment legs 373 are formed between the

forming shoulder 382 of the third die 371 and the annular forming surface 376 of the first die 369 and the proximally extending portion 374 of the attachment legs 357' is formed between the exterior of the first die 369 and the counterbore 381 of the third die 371, as shown in Fig. 30H.

The tubular member 356 of the anastomosis fitting 355, which has been formed to its deployed position, is withdrawn from the first die 369 and is grasped with the special grasping tool 372. The grasping tool 372 has expandable jaws 384, 385 which fit between the graft vessel 354 and the inner lumen 359 of the tubular member 356. The jaws 384, 385 are shaped like sectors of a cylinder with an exterior diameter approximately equal to the inner diameter of the tubular member 356. Each of the sectors is somewhat smaller than a semi-cylinder so that the jaws 384, 385 can be collapsed small enough to easily fit within the internal lumen 359 of tubular member 357. A thumbscrew, or other suitable mechanism, on the grasping tool 372 expands the jaws 384, 385 so that they bear against the interior surface of the tubular member 356. Lugs 386 corresponding to the three holes 363 in the proximal end of the tubular member 356 engage the three holes 363 to enhance the grasping tool's grip on the tubular member 356.

Using the grasping tool 382, the bent attachment legs 357' and the distal end 360 of the tubular member, with the everted end 259 of the graft vessel 254 attached, are inserted through an opening 267 in the target vessel wall 255 that has previously been made with an aortic punch or similar instrument, as shown in Fig. 30I. The opening 367 is preferably made so that it is approximately the size of the external diameter of the tubular member 356 to provide compression around the everted end 259 of the graft vessel 254 to help create an anastomotic seal. Since the opening 267 is slightly smaller than the diameter of the bent attachment legs 357', the opening 267 must be stretched slightly to allow the attachment legs 357' to pass through the opening 267. Insertion can be effectively accomplished by passing two of the attachment legs 357' through the opening 267 in the target

vessel wall 255, then gently stretching the opening 267 with forceps to insert the remaining attachment legs 357'.

Once the attachment legs 357' have been passed through the opening 267 in the target vessel wall 255, the inner tubular member 356 is pulled back with enough force to cause the sharpened distal ends 361' of the attachment legs 357' to pierce the interior surface 257 of the target vessel wall 255. This action also serves to approximate the everted end 259 of the graft vessel 254 with the interior surface 257 of the target vessel 255 to effect the desired intimal surface-to-intimal surface approximation between the two vessels. The sharpened distal ends 361' of the attachment legs 357' can be assisted in piercing the target vessel wall 255 by pressing on the exterior 258 of the target vessel wall 255 with an elastomeric-tipped probe while maintaining some tension on the tubular body 356 of the fitting using the grasping tool 372. The anastomosis is completed by sliding the central orifice 364 of the outer flange 358 over the exterior surface of the tubular member 356 and moving the outer flange 358 distally while keeping some tension on the tubular member 356 to create tissue compression at the anastomosis site to assure an anastomotic seal. A probe 387 with a distal pushing surface 388 can be used to press the outer flange 358 onto the tubular member 356. The distal pushing surface 388 of the probe 387 is slotted and angled so that it can be used from the side of the grasping tool 372. The proximally directed distal ends 361' of the attachment legs 357' pass through the holes 363 around the periphery of the outer flange 358, as shown in Fig. 30J. If desired, the distal surface 367 of the outer flange 358 can be made somewhat concave to help create a hemodynamically efficient transition between the target vessel lumen 256 and the graft vessel lumen 249. The self-locking retaining washer 365 of the outer flange 358 locks into the circumferential groove 362 on the exterior of the tubular member 356 to permanently hold the outer flange 358 in a fixed position relative to the tubular member 356.

Fig. 31A shows a further embodiment of an anastomosis device 390 according to the invention that combines a fastening flange 391 with a plurality of staple members 392. The device 390 includes a fastening flange 391 which has a central orifice 393 of sufficient size to accommodate the external diameter of the graft vessel 254. The external diameter of a saphenous vein graft used in CABG surgery can range from 3 to 10 mm. The fastening flange 391 and the central orifice 393 can be made circular, as shown in Fig. 31B, for making a typical right angle anastomosis. Alternatively, the fastening flange 391 and/or the central orifice 393 can be made elliptical, oval, egg-shaped or tear drop shaped, as shown in Figs. 31C and 31D, for making a more hemodynamically efficient angled Anastomosis. Many of the anastomotic fittings and staples described herein lend themselves to noncircular configurations, such as elliptical or teardrop shapes. Each of the detailed descriptions of the various embodiments should be assumed to include noncircular flanges as an optional configuration. The fastening flange 391 is made with a distal surface 394 over which the free end 259 of the graft vessel 254 is everted, as shown in Fig. 31A. The fastening flange 391 can be made with an annular ridge 395 or with other features on its outer surface to help attach the everted end 259 of the graft vessel 254 to the flange 391. The distal surface 394 of the fastening flange 391 may be contoured to provide a close fit between the everted edge 259 of the graft vessel 254 and the exterior wall 258 of the target vessel 255. If the target vessel 254 diameter is very large compared to the diameter of the graft vessel 254, as in a coronary artery bypass graft to ascending aorta anastomosis, then a planar distal surface 394 on the fastening flange 391 may sufficiently approximate the exterior surface 258 of the target vessel 255. However, if the graft vessel 254 diameter is closer to the diameter of the target vessel 255, as in a bypass graft to coronary artery anastomosis, then the fastening flange 391 should be made with a cylindrical or saddle-shaped contour on the distal surface 394 that closely approximates the exterior contour of the target vessel 255.

The fastening flange 391 should be made of a biocompatible material such as stainless steel, titanium alloys, or a biocompatible polymer. The fastening flange 391 acts as an external stent which holds the anastomosis site open and patent, so the flange material is preferably rigid or at least sufficiently resilient to hold its intended shape.

The fastening flange 391 with the everted end 259 of the graft vessel 254 attached to it is fastened to the exterior wall 258 of the target vessel 255 with the central orifice 393 aligned with an opening 267 in the target vessel wall 255 that has been previously made using a vessel punch or similar instrument. The fastening flange 391 is held in place by a plurality of fastening members 292, which in this embodiment take the form of metallic surgical staples 292 which are shown in Fig. 31E. The surgical staples 292, preferably 4-12 of them arranged around the periphery of the fastening flange 391, traverse from the proximal side 396 to the distal side 394 of the flange 391, then pierce the everted graft vessel wall 259 and the wall of the target vessel 255. It is preferable that the staples 292 pass through premade holes 397 in the fastening flange 391, however, if the fastening flange 391 is made of a resilient material, the staples 392 may pierce the flange 391 as they pass through it. The distal ends 398 of the staples 392 are deformed by a forming device or anvil against the interior surface 257 of the target vessel wall 255 to hold the device in place to complete the anastomosis.

The staples 392 can be specially constructed so that they will deform at the appropriate point on the attachment legs 399. One way to achieve this desired result is to make the core 400 of the staple 392, including the crossbar 401 and the two attachment legs 399, of a soft deformable metal such as annealed stainless steel. A proximal portion of each of the attachment legs 399 is surrounded by a stiffening sleeve 402 that is made of a more rigid material, such as hard stainless steel hypodermic tubing. The stiffening sleeves 402 prevent the proximal portion of the attachment legs 392 from deforming. The stiffening sleeves 402 should be sized so that

their length corresponds to slightly less than the combined thickness of the flange 391, the graft vessel wall 259 and the target vessel wall 255 so that, when the attachment legs 399 are bent at the distal edge of the stiffening sleeves 402, a tailored amount of compression is applied at the anastomotic site to ensure a leak proof attachment without excessive crushing of the tissue which could lead to necrosis.

Alternatively, the staples could be manufactured with attachment legs 399 having a thicker cross section proximal portion and a thinner cross section distal portion so that the attachment legs 399 will deform at the appropriate point.

The anastomosis device 390 is part of a complete anastomosis system that includes a specially adapted application device 403 for creating the anastomosis. The distal end of the application device 403 can be seen in Fig. 31A. A staple driver 404 pushes the staples 392 from the proximal end, while a specially constructed anvil 405 reaches into the lumen 256 of the target vessel 255 to deform the distal ends 398 of the attachment legs 399. The staple driver 404 has an annular distal surface 406 which presses against the crossbars 401 of the staples 392. In one embodiment, the staple driver 404 can be tubular with an internal lumen 407 large enough to accommodate the graft vessel 254, allowing the graft vessel 254 to be passed through the staple driver 404 from the proximal end to the distal end. Alternatively, the staple driver 404 can be made with a C-shaped cross section with a side opening that is large enough to pass the graft vessel through from the side. The anvil 405 is articulated on the distal end of an elongated shaft 408. The shaft 408 is long and narrow enough to pass through the lumen 249 of the graft vessel 254 from the free end of the graft. The anvil 405 is passed through the graft vessel lumen 249 in an orientation axially aligned with of the shaft 408 and, once it is in the lumen 256 of the target vessel 255, it is articulated at 90°, as shown in Fig. 31A. A cylindrical or olive-shaped centering element 409, such as an inflatable centering balloon on the shaft 408, can be used to center the shaft 408 of the anvil 405 within the lumen 249 of the graft

vessel 254 and within the central orifice 393 of the flange 291. The anvil 305 can now be rotated about the shaft 308 to deform the distal ends 398 of the attachment legs 399.

The application device 403 can operate by two different mechanisms. It can operate in a manner similar to other surgical staplers by aligning the staple driver 404 and the anvil 405 on opposite ends of a staple 292, then moving them axially toward one another, by moving either the staple driver 404 distally, or the anvil 405 proximally, or a combination of the two motions. This relative movement compresses the staple leg 399 in between the anvil 405 and the staple driver 404 and deforms it to hold the anastomosis together. An alternative mechanism involves rotating the anvil 405 with respect to the staple driver 404 and the anastomosis device 390 like a wiper to sequentially bend over the distal ends 398 of the staples 392, as shown in Fig. 31F. The staple driver 404 may be equipped with a gripping means for holding the fastening flange 391 to prevent any resultant torque on the flange 391 from being transferred to the delicate vascular tissues. Alternatively, the olive-shaped centering element 409 or balloon could have sufficient bearing surface that the delicate vascular tissues do not suffer any significant damage. An alternative embodiment would have two or more wiper anvil elements 405 spaced symmetrically about the axis of the shaft 408, so that opposing staples 392 are bent simultaneously, reducing the net torque applied to the centering element 409 and the tissues.

Fig. 32A shows another variation of the anastomosis device of Fig. 31A. This variation of the anastomosis device 410 uses preformed spring-like fastening staples 411. As in the previously described device, the anastomosis device 410 includes a fastening flange 412 with a central orifice 413 of sufficient size to accommodate the exterior diameter of the graft vessel 254. A plurality of preformed fastening staples 411 are arranged around the periphery of the fastening flange 412. Preferably, the staples 411 are preloaded into premade axial holes 414 through the fastening flange 412. The staples 411 should be made of a highly resilient biocompatible spring

material, such as spring-tempered stainless steel or titanium alloys. Superelastic materials, such as nickel-titanium alloys, can also be used for forming the spring-like staples. Information about the composition and treatment of

5 superelastic metal alloys useful in the manufacture of the spring like staples can be found in U.S. patent 4,665,906, entitled Medical Devices Incorporating SIM Alloy Elements, the entire disclosure of which is hereby incorporated by reference. Two alternate forms for the spring-like staples

10 411, 420 are shown in Figs. 32B and 32C. Fig. 32B shows a single staple 411 which has one attachment leg 415. The distal end 416 of the attachment leg 415 is sharpened to easily pierce the blood vessel walls. A distal portion 417 of the attachment leg 415 is bent at an acute angle with respect

15 to a central portion 418 of the leg 415. Similarly, a proximal portion 419 of the leg 415 is bent at an acute angle with respect to the central portion 418. The proximal portion 419 and the distal portion 417 of the staple 411 can be angled in the same direction with respect to the central portion 418

20 to make a C-shaped staple, as shown in Fig. 32B, or the proximal 419 and distal 417 portions can be angled in opposite directions to create a Z-shaped staple. Fig. 32C shows a double staple 420 which has two parallel attachment legs 415. The distal end 415 of each attachment leg 415 is sharpened to

25 easily pierce the blood vessel walls. The distal portions 417 of the attachment legs 415 are bent at an acute angle with respect to the central portions 418 of the legs 415. The proximal portions 419 of the legs 415 are also bent at an acute angle with respect to the central portions 418. The

30 proximal portions 419 of the attachment legs 415 are linked together by a crossbar 421. The double staple 420 has an advantage in that the crossbar 421 linking the two attachment legs 415 keeps the staple 420 aligned within the fastening flange 412. When using double staples 420 with the fastening

35 flange 412, the axial holes 414 through the flange 412 should be made as pairs of holes 414 spaced apart by approximately the length of the crossbar 421 of the staple 420. Similar to the single staple 411 of Fig. 32B, the double staple 420 can

be made with the proximal portions 419 and the distal portions 417 of the attachment legs 415 angled in the same direction with respect to the central portions 418 to make a C-shaped staple, when viewed from the side, or the proximal 419 and distal 417 portions can be angled in opposite directions to create a Z-shaped staple as shown in Fig. 32C.

The operation of either staple version can be understood from the sequence of drawings in Figs. 32D, 32E, and 32F. The following operational description using the single staple 411 of Fig. 32B is, therefore equally applicable to the double staple 420 of Fig. 32C. The staples 411 are preferably preloaded into the fastening flange 412 so that the distal bend 427 of the staple legs 415 is captured within and straightened by the hole 414 through the flange 412. The resilience of the spring material prevents the staple legs 415 from taking a permanent set when they are straightened out to load them into the holes 414 in the flange 412.

If a superelastic nickel-titanium alloy is used for the spring-like staples 411, then the shape-memory property of the alloy can be used to facilitate loading the staples 411 into the flange 412. To do this, the staple 411 would first be annealed in the desired shape for the final staple. Then, the staple 411 would be plastically deformed below its transition temperature to straighten out the distal bend 427. The straightened staples 411 are easily inserted into the holes 414 in the flange 412. Finally, the staples 411 are heated above their shape-memory transition temperature to make them resume their annealed shape. Preferably, the transition temperature is below body temperature so that the alloy of the staple 411 is in its martensitic or superelastic phase when the staple 411 is deployed within the body. Since the distal bend 427 is captured within the hole 414 in the flange 412, it is held straight until the staple 411 is deployed in the following steps.

The free end 259 of the graft vessel 254 is everted over the distal surface 422 of the fastening flange 412, as shown in Fig. 32D, and the device 410 is aligned with an opening 267 that has been previously made in the target vessel

wall 255. To help align the central orifice 413 of the flange 412 with the opening 267 in the target vessel 255, an alignment device 423 can be inserted through the lumen 249 of the graft vessel 254 from the opposite end of the graft. The alignment device 423 has a narrow, elongated shaft 424 which fits through the lumen 249 of the graft vessel 254 and an atraumatic centering element 425, such as an inflatable centering balloon on the distal end of the shaft 424. The centering element 425 serves to align the central orifice 413 of the flange 412 and the graft vessel lumen 249 with the opening 267 in the wall of the graft vessel 255. The alignment device 425 can also be used to apply a mild amount of traction on the target vessel wall 255 to better approximate the everted end 259 of the graft vessel 254 and the target vessel 255 when making the anastomosis. Alternatively, the centering element 425 could be replaced with a vessel punch introduced through the graft vessel lumen 249, as in the embodiments described in connection with Figs. 2-5.

Once the everted end 259 of the graft vessel 254 and the target vessel 255 have been properly approximated, the staple driver 426 is advanced distally, as shown in Fig. 32E. The distal ends 416 of the staples 411 pierce the everted graft vessel wall 259 and the target vessel wall 255 and the distal portion 417 of the attachment legs 415 traverses the vessel walls in a linear path. As the distal bend 427 of the attachment legs 415 exit the hole 414 in the fastening flange 412, the distal portions 417 begin to resume their acute angle bend. By the time the staple driver 426 reaches its most distal position, the distal bend 427 of the attachment legs 415 is fully reconstituted within the lumen 256 of the target vessel 255. When the staple driver 426 is withdrawn, the spring action of the proximal bend 428 in the attachment legs 415 pulls the staple 411 back slightly to embed the distal portions 417 of the attachment legs 415 into the interior surface 257 of the target vessel wall 255, as shown in Fig. 32F. The spring action of the staples 411 also serves to exert compressive force between the fastening flange 412 and

the target vessel wall 255 to assure a leak proof and secure attachment.

During the manufacture of the staples 411, the distal bends 427 on the staple attachment legs 415 can be made with almost any desired orientation. The distal bends 427 can be oriented to turn the distal portion 417 of the attachment legs 415 toward the opening 267 in the target vessel wall 255, as shown in Fig. 32F, or the distal portions 417 can be oriented pointing away from the opening 267. Alternatively, the distal portions 417 can be aligned so that they bend tangentially to the opening 267. The tangential distal portions can be oriented so that they cross one another. Perhaps more advantageously, the tangential distal portions 417 can be oriented so that they all bend in the same direction, as shown in Fig. 32G, so that a more complete gap-free seal is made all around the periphery of the anastomosis.

Figs. 33A-33D and 34A-34D show two variations of an anastomosis device 430 having a fastening flange 431 and a plurality of S-shaped staple members 432 formed from a superelastic metal alloy such as a nickel-titanium alloy. The fastening flange 431 has a central orifice 433 which is sized to accommodate the exterior diameter of the graft vessel 254. The fastening flange 431 has an annular distal ridge 434 and an annular proximal ridge 435 around its outer surface. There are a plurality of holes 436 arranged in a circle around the periphery of the central orifice 433 of the flange 431 passing through the flange 431 from the proximal surface to the distal surface 438. Each of the holes 436 is sized to slidably receive one of the S-shaped staple members 432. There are a plurality of cylindrical lugs 439 extending from the proximal surface 437 of the flange 431. Preferably, the lugs 439 are arranged in a circle concentric with the central orifice 433 and there are an equal number of lugs 439 to the number of holes 436 in the flange 431 with the lugs 439 spaced equidistant from adjacent holes 436.

The S-shaped superelastic alloy staple members 432 are shown in perspective Fig. 33D. The staple member 432 is

formed with a straight central segment 440 that is attached to a hook-shaped distal segment 441 and a proximal segment 442 which bends at an angle just under 90 degrees from the central segment 440 in a plane that is approximately at a right angle to the plane defined by the hook-shaped distal segment 441.

The distal tip 443 of the hook-shaped distal segment 441 is sharpened to easily penetrate the graft vessel wall 254 and the target vessel wall 255. Fig. 34D shows a slight variation of the staple member 432 of Fig. 33D. This variation differs from the previous one in that the distal segment 444 is bent at an acute angle to the central segment rather than being a fully formed hook. The S-shaped staples 432 are annealed in the desired configuration so that they will retain the annealed shape. The extremely resilient nature of the superelastic alloy allows the staple members 432 to be completely straightened without causing plastic deformation of the staples so that they will return to their annealed shape.

The anastomosis device 430 is prepared for use by passing the graft vessel 254 through the central orifice 433 of the fastening flange 431 then everting the distal end 259 of the graft vessel 254 over the distal surface 437 of the flange 431. A suture 445 can be tied around the everted end 259 of the graft vessel 254 to secure it to the flange 431. The distal ridge 434 of the flange 431 prevents the tied graft vessel 259 from slipping off of the flange 431. Next, the staple members 432 are straightened and passed through the holes 436 in the flange 431 from the proximal surface 437 to the distal surface 438. The distal curve 441 of the staples 432 is restrained in the straightened position by the sliding fit with the holes 436 in the flange 431. When the staples 432 emerge from the distal surface 438 of the flange 431, they pierce the everted wall 259 of the graft vessel 254. At this point the fastening flange 431 with the everted end 259 of graft vessel 254 attached to it is approximated to the exterior surface 258 of the target vessel 255 with the central orifice 433 and the lumen 249 of the graft vessel 254 centered on an opening 267 that has been made in the wall of the target

vessel 255. The distal ends 443 of the staple members 432 pass through the opening 267 in the target vessel wall 255.

Once the graft vessel 254 and the target vessel 255 are properly approximated, an annular staple driver 446 is used to push the staple members 432 distally through the holes 436 in the flange 431 so that they emerge into the lumen 256 of the target vessel 255. As the distal ends 443 of the staple members 431 emerge from the distal surface 438 of the flange 431 the distal segments 441 resume their annealed shape. The hook-shaped distal segments 441 of the staple members 431 in Fig. 33D curve back toward the interior surface 257 of the target vessel and penetrate the target vessel wall 255. The proximal segments 442 of the staple members 432 are positioned between the lugs 439 on the proximal surface 437 of the flange 431 to lock the staples 432 from rotating with respect to the flange 431. Fig. 33C shows a proximal view of the anastomosis device 430 with the staple members 432 deployed. This view is shown without the graft vessel or the target vessel present for the sake of clarity. As best seen in Fig. 33B, the acute angle of the proximal segment 442 acts like a spring to pull back on the staple member 432 to help the distal segment 441 to pierce the target vessel wall 255 and to help create compression between the flange 431 and the target vessel wall 255 to create a leak proof anastomotic seal between the graft vessel 254 and the target vessel 255.

The deployment of the anastomosis device in Figs. 34A-34D is essentially the same as just described up until the point when the distal ends 444 of the staple members 432 begin to emerge into the target vessel lumen 256. As the distal ends 443 of the staple members 432 emerge from the distal surface 438 of the fastening flange 431, they resume their acute angle bend. Rather than penetrating the target vessel wall 255, the distal segments 444 of the staple member 432 align themselves flat against the interior surface 257 of the target vessel 255 and press against the vessel wall 255, compressively clamping the fastening flange 431 and the everted end 259 of the graft vessel 254 to the target vessel wall 255. The acute angle of the proximal segment 442 acts

like a spring to pull back on the staple member 432 to keep the distal segment 444 snug against the interior surface 257 of the target vessel wall 255.

Figs. 35A-35F show another variation of an anastomosis device 447 using a fastening flange 448 and attachment staple 449 combination. The fastening flange 448 is a cylindrical member with an internal lumen 450 large enough to accommodate the external diameter of the graft vessel 254. The flange 448 has a distal surface 451 over which the free end 254 of the graft vessel 259 may be everted. An annular ridge 452 around the outer surface of the flange 448 at the distal end helps to hold the everted graft vessel 259 in place and serves as part of a locking mechanism for the attachment staples 449, as will be described below. The attachment staples 449 are in the form of U-shaped hooks with barbed points 453 on their distal tips. Each staple 449 has a proximal portion 454 which is slidably received within an axial hole 456 through the cylindrical wall 457 of the fastening flange 448. The proximal end 455 of the proximal portion 454 is sharpened for easily piercing the tissue of the graft vessel wall 254. A U-shaped bend 458 connects the proximal portion 454 of the staple 449 to the barbed, pointed distal portion 453.

The anastomosis device 447 is applied by removing the U-shaped staples 449 from the flange 448. The end 259 of the graft vessel 254 is passed through the internal lumen 450 of the flange 448 until the graft vessel 254 extends a short distance from the distal end 459 of the flange 448. Then, the end 259 of the graft vessel 254 is everted back over the distal end 259 of the flange 448. Once the graft vessel 254 is everted over the flange 448, the staples 449 are reinserted into the holes 456 in the flange 458 by piercing the proximal end 445 through the everted wall 259 of the graft vessel 254. Marks or other visual indications can be provided on the side of the cylindrical flange 448 to aid in aligning the proximal ends 455 of the staples 449 with the holes 456. The proximal portions 454 of the staples 449 are partially advanced into the flange 448 as shown in Fig. 35B. The U-shaped ends 458 of

the staples 449 are inserted through an opening 267 in the wall of the target vessel 255 which has previously been made using a vessel punch or similar instrument. Two alternate methods can be used for inserting the staples 449 through the opening 267 in the target vessel wall 255. In the first method, shown in Fig. 35C, the U-shaped ends 458 of the staples are extended from the cylindrical flange 448 far enough that they easily deflect inward toward the center of the opening 267 in the target vessel wall 255 when they contact the edge of the opening 267 so that they can be simultaneously inserted through the opening 267. In the second method, the U-shaped ends 458 of the staples 449 are rotated, as shown in Fig. 35D, so that the U-shaped ends 458 all fit within a circle that will pass through the opening 267 in the target vessel wall 255. Once the U-shaped ends 458 of the staples 449 are within the lumen 256 of the target vessel 255, the staples 449 can be rotated so that the U-shaped ends 458 extend radially outward from the fastening flange 448. The distal surface 459 of the cylindrical flange 448 with the everted graft vessel 259 attached to it is approximated to the exterior surface 258 of the target vessel 255, then the staples 449 are withdrawn in the proximal direction so that the barbed, pointed distal ends 453 pierce the target vessel wall 255. The distal portion 460 of the staple 449 passes through the target vessel 255 wall in a linear path, then pierces the everted edge 259 of the graft vessel wall 254 a second time. When the barbed end 453 of staples 449 pass the annular ridge 452 on the distal end 459 of the flange 448 the barbs 453 engage the proximal surface of the ridge 452, locking the staples 448 in position to permanently attach the anastomotic device 447 in place. The excess length on the proximal portion 454 of the U-shaped staples 449 may be cut off flush with the proximal end 461 of the cylindrical flange 448. Alternatively, the proximal portion 454 of the staple 449 can be bent over at the proximal end 461 of the cylindrical flange 448 for a second means of attachment, then the excess length cut off.

Two alternative versions of the anastomosis device of Fig. 35A, using different locking means for the U-shaped staples, are shown in Figs. 36A-36C and 37A-37C. Fig. 36A shows an anastomosis device 462 with a fastening flange 463 and a plurality of non-barbed U-shaped staples 464 and a locking collar 465 for locking the U-shaped staples 464 onto the fastening flange 463. The flange 463 and the staples 464 are applied in much the same way as described above for the previous embodiment, by inserting the staples 464 through the opening 267 in the target vessel 255 and withdrawing them in the proximal direction so that the distal ends 466 of the staples 464 pierce the target vessel wall 255 and emerge alongside the outer surface of the fastening flange 463. A locking collar 465 is then pressed onto the proximal end 467 of the fastening flange 463, as shown in Fig. 36B, crimping the distal ends 466 of the staples 464 and locking them to the flange 463 in the process. The excess length of the proximal portion 468 of the staples 464 is cut off flush with the proximal end 467 of the fastening flange 463 to complete the anastomosis, as shown in Fig. 36C.

Fig. 37A shows a second anastomosis fitting 469 with non-barbed U-shaped staples 470 and a locking collar 471 for locking the U-shaped staples onto the fastening flange 472 of the fitting 469. The fastening flange 472 in this embodiment has a conical surface 473 on the outer surface of the flange 472 proximal to the distal rim 474 of the flange 472. The proximal end 475 of the fastening flange 472 has a series of parallel annular locking ridges 476 around its exterior surface. A locking collar 471 has an interior taper 477 which matches the conical taper 473 of the fastening flange 472 and a series of parallel locking ridges 478 on the proximal end. After the flange 472 and the staples 470 have been applied as described above, the locking collar 471 is pressed onto the flange 472, as in Fig. 37B. The distal portion 479 of the U-shaped staple 470 is wedged between the mating conical tapers 473, 477. The locking ridges 478 of the locking collar 471 engage the locking ridges 476 of the flange 472 to permanently lock the anastomosis device 469 in place and the

anastomosis is completed by cutting off the proximal portions 480 of the staples 470 flush with the proximal end of the flange 475, as shown in Fig. 37C.

The anastomosis fittings of Figs. 33-37 may also be manufactured using staple elements made of a highly elastic material, such as a superelastic nickel-titanium alloy, so that the staples may be preformed with U-shaped ends which can be straightened and loaded into the holes in the fastening flange. The staples would be deployed by pushing them out the distal end of the flange so that they pass through the wall of the graft vessel into the target vessel, after which, they resume their U shape within the lumen of the target vessel. The highly elastic staple elements could be locked onto the fastening flange using any of the methods described in connection with Figs. 33-37.

Figs. 38A-38C and 39A-39C show one-piece versions of an anastomosis device using a fastening flange and attachment staple combination. Fig. 38A shows an anastomosis device 481 that has a fastening flange 482 and integrally formed staple members 483. The fastening flange 482 is a flat annular ring which may be formed from a flat sheet of a biocompatible metal. The staple members 483, which may be formed from the same sheet of metal, attach to the inner diameter 484 of the ring 482 and are initially bent 90° from the flange 482 so that they extend in the distal direction, as shown in Fig. 38B. The inner diameter 484 of the flange fits over a tubular inner member 485 of an application tool 486. The graft vessel 254 is passed through an inner lumen 487 within the tubular member 485 and then the end 259 of the graft vessel 254 is everted over the distal end 488 of the tubular member 485. The application tool 486 is used to approximate the end 259 of the graft vessel 254 to an opening 267 that has previously been made in the wall of the target vessel 255. A tubular staple driver 489 slides telescopically over the exterior of the tubular inner member 485. The fastening flange 482 is moved distally by sliding the staple driver 489 axially with respect to the inner tubular member 485, which forces the sharpened distal ends 490 of the integral staple legs 483

through the everted wall 259 of the graft vessel 254 and the wall of the target vessel 255. Once the staple legs 483 have traversed the graft vessel 254 and target vessel walls 255, the distal ends 490 of the staple legs 483 are deformed to lock the anastomosis device 481 in place as shown in Fig. 38C.

Different methods can be used for deforming the distal ends 490 of the staple legs 483 to attach the anastomosis device 481. An articulating anvil, similar to the one described in Fig. 31A can be inserted through the lumen 249 of the graft vessel 254 to work cooperatively with the staple driver 489 to deform the distal ends 490 of the staple legs 483. Alternatively, the fastening flange 482 and the staple legs 483 can be made of a spring-like elastic or superelastic alloy and preformed into their final desired shape. The inner tubular member 485 of the staple application device 486 seen in Fig. 38B holds the preformed distal bend 491 in the staple legs 483 straight until the anastomosis device 481 is deployed by the staple driver 489. Another alternative is to make the anastomosis device 481 and the staple legs 483 from a shape-memory alloy, such as a nickel-titanium. The staple legs 483 are annealed in their final shape. Then, the staple legs 483 are plastically deformed below the material's transition temperature to straighten out the distal bends 491. The straightened staple legs 483 are driven through the walls of the graft vessel 254 and the target vessel 255 and the staple legs 483 are heated above their shape-memory transition temperature to make them resume their annealed shape. The material is preferably chosen so that the transition temperature is at or near body temperature so that heating the staple above the transition temperature does not cause damage to the delicate vascular tissues.

Fig. 39A shows an additional anastomosis device 492 that has a fastening flange 493 and integrally formed staple members 494. The fastening flange 493 in this case is a cylindrical ring formed from a tube of a biocompatible metal. The staple members 494 are attached to the distal edge of the cylindrical fastening flange 493. Optionally, there are also

proximal fastening members attached to the proximal edge of the cylindrical fastening flange 493. This variation of the anastomosis device can be applied with any of the methods just described in connection with Figs. 37A-37C. If the  
5 anastomosis device 492 has been made of an elastic or superelastic alloy, the optional proximal fastening members 495 can serve as spring members to compress the anastomotic attachment, similar to the proximal portions of the spring-like staples 411, 420 described in connection with  
10 Figs. 32A-32F.

Figs. 40A-40D show a two-piece version of an anastomosis device 496 having a fastening flange and integrally formed staple members. In this case, the fastening flange of the device is formed of two concentric cylindrical  
15 flange rings 497, 498. A plurality of interlocking staple members 499, 500 extend from the distal edges of both cylindrical flange rings 497, 498. Preferably, the staple members 499, 500 are integrally formed with the cylindrical flange rings 497, 498. The staple members 499 of the inner  
20 flange ring 497 are angled so that they spiral downward from the ring 497 in a clockwise direction. The staple members 500 of the outer flange ring 498 are oppositely angled so that they spiral downward from the ring 497 in a counterclockwise direction. Corresponding locking features 501, 502 on the  
25 inner surface of the outer flange ring 498 and on the outer surface of the inner flange ring 497 are capable of locking the two flange rings 498, 497 together in a fixed position. Indentations on one flange ring, with corresponding detents on the other flange ring are one of the many possibilities for  
30 the locking features 501, 502.

The anastomosis device 496 is applied by separately placing first the outer flange ring 498, then the inner flange ring 497 around the distal end 259 of the graft vessel 254. The end 259 of the graft vessel 254 is then everted and  
35 approximated to the exterior wall 258 of the target vessel 255 surrounding an opening 267 which has been previously made in the wall, as shown in Fig. 40C. The inner ring 497 is moved distally along the graft vessel 497 until the points of the

staple members 499 contact the everted vessel wall 259. The inner ring 497 is pressed into the everted graft vessel wall 259 and simultaneously rotated in a clockwise direction, thereby driving the staple members 497 through the graft vessel wall 259 and the target vessel wall 255. Next, the outer ring 498 is moved distally along the graft vessel 254 until it is concentric with the inner ring 497. Then the outer ring 498 is pressed into the everted graft vessel wall 259 and simultaneously rotated in a counterclockwise direction, driving the staple members 500 through the graft vessel wall 259 and the target vessel wall 255. When the locking features 501 of the outer ring 498 coincide with the locking features 502 of the inner ring 497, the outer 498 and inner 497 rings become locked together. As the flange rings 497, 498 are rotated in opposite directions, the staple members 499, 500 of the inner 497 and outer rings 498 penetrate the vessel walls in opposite directions as shown in Fig. 40C, effectively locking the anastomosis device 496 to the exterior 258 of the target vessel 255.

Alternatively, the inner 497 and outer rings 498 of the flange can be applied simultaneously to the everted end 259 of the graft vessel 254 by arranging the rings 497, 498 concentrically, then pressing the staple members 499, 500 into the graft vessel wall 259 while counter-rotating the inner 497 and outer 498 rings. This could best be done with an instrument that holds and rotates the inner 497 and outer 498 rings mechanically.

Figs. 41A-41E show another approach to making an anastomosis device 503 having a fastening flange 504 and a plurality of individual staple members 505. The method of deployment used in this embodiment allows the staple members 505 to be made of a normally elastic metal alloy, such as spring-tempered stainless steel. The fastening flange 504 in this embodiment is a tubular element with a central orifice 506 which is surrounded by an inner wall 507, a distal surface 508, and an outer wall 509 defining an annular space 510 between the inner 507 and outer walls 509. The annular distal surface interconnects the inner 507 and outer 509 walls. The

annular space 510 is sized to fit the staple members 505 prior to deployment, as shown in Fig. 41A. A staple application tool 511 has an annular staple driver 512 which fits into the annular space 510 within the flange 504. The distal surface 508 and the inner wall 507 of the flange 504 is slotted with pairs of L-shaped slots 513 to allow penetration of the staple members 505 through the distal surface 508.

Alternatively, the flange 504 may have a solid body and the annular space 510 can be replaced by a series of individual staple slots formed in the body of the flange by a process like electrical discharge machining. The individual staple slots can each be sized to fit a single staple member 505. Each individual staple slot should communicate with a single slot or a pair of slots in the distal surface 508 of the fastening flange 504 for proper deployment of the staple members 505, depending on whether the staple members are single or double-leg staples. In this case, the annular staple driver 512 of the application tool 511 must be replaced with an array of individual staple drivers sized to fit into the individual staple slots.

The staple members 505 for this embodiment can be made as J-shaped, single-leg staples 505' or as U-shaped, double-leg staples 505. When viewed from the side, the single 505' and double-leg staples 505 are both roughly the shape of an inverted J, as seen in Fig. 41A. The double-leg staples 505 combine two such J-shaped staple legs 514 with a crossbar 515 that connects the proximal ends of the staple legs 514 to form staples 505 that are roughly U-shaped when viewed from the front or from the top, as in Fig. 41E. The staple legs 514 are formed with a central segment 516 that is attached at an acute angle to a proximal segment 517. A short intermediate segment 518 may be used to connect the proximal segment 517 to the central segment 516 of the staple member 505. The proximal end of each of the proximal segments 517 is joined to the crossbar 515 of the staple member 505. A distal segment 519 is attached to the central segment 516 at an obtuse angle so that it is approximately parallel to the proximal segment 517. The distal end 520 of the distal

segment 519 is sharpened to easily penetrate the graft vessel wall 259.

5 The anastomosis device 503 is prepared by passing the graft vessel 254 through the central orifice 506 of the fastening flange 504 and everting it over the distal surface 508 of the flange 504. As an alternative to the loop of suture described in previous embodiments of the device, a vessel cap 521 may be used to secure the everted graft vessel 259 to the fastening flange 509. The vessel cap 521 is a  
10 toroidal ring with an L-shaped cross section that fits around the outer diameter of the distal surface 508 of the fastening flange 504 and holds the everted end 259 of the graft vessel 254 in place.

Next, the fastening flange 504 with the everted end  
15 259 of the graft vessel 254 attached is approximated to the exterior 258 of the target vessel 255 with the central orifice 506 aligned with an opening 267 through the target vessel wall 255, as shown in Fig. 41A. The staple driver 512 is then advanced in the distal direction to press against the  
20 attachment legs 514 of the staple members 505 and force the distal ends 520 of the staple members 505 through the slots 513 in the distal end 508 of the fastening flange 504 to pierce the graft vessel wall 259 and enter the target vessel lumen 256 through the opening 267 in the target vessel wall  
25 255, as shown in Fig. 41B. As the staple driver 512 is advanced further the crossbar 515 of the staple member 505 contacts the distal wall 508 of the fastening flange 504 and the staple member 505 begins to rotate about the point of contact, as shown in Fig. 41C. The distal segments 519 of the  
30 staple members 505 capture the target vessel wall 255 and pull it tight against the distal surface 508 of the fastening flange 504, as shown in Fig. 41D, to form a leak proof anastomotic seal between the everted graft vessel wall 259 and the target vessel 255.

35 Figs. 42A-42D illustrate another one-piece embodiment of the anastomosis device 522 with a fastening flange 523 and attached staple members 524. Preferably, the anastomosis device 522 is made from a deformable biocompatible

metal, such as a stainless steel alloy, a titanium alloy or a cobalt alloy. If desired a surface coating can be applied to the anastomosis device to improve the biocompatibility or other material characteristics.

5           In contrast to some of the previously described embodiments, in this version of the anastomosis device 522, the fastening flange 523 resides on the interior surface 258, of the target vessel wall 255 when the anastomosis is completed. To avoid any problems with hemolysis,  
10 thrombogenesis or foreign body reactions, the total mass of the fastening flange 523 has been reduced to an absolute minimum to reduce the amount of foreign material within the target vessel lumen 256.

          The fastening flange 523 is in the form of a wire  
15 ring 523 with an internal diameter which when fully extended is just slightly larger than the diameter of the graft vessel 254 and of the opening 267 made in the target vessel wall 255. Initially, the wire ring 523 has a rippled wave-like shape to reduce the diameter of the ring 523 so that it will easily fit  
20 through the opening 267 in the target vessel wall 255. A plurality of staple members 524 extend from the wire ring 523 in the proximal direction. In the illustrative embodiment shown in Fig. 42A, there are nine staple members attached to the wire ring fastening flange 523. Other variations of the  
25 anastomosis device 522 might typically have from four to twelve staple members 524 depending on the size of the vessels to be joined and the security of attachment required in the particular application. The staple members 524 can be formed integrally with the wire ring fastening flange 523 or the  
30 staple members 524 could be attached to the ring 523 by welding or brazing methods. The proximal ends 525 of the staple members 524 are sharpened to easily pierce the target vessel wall 255 and the graft vessel wall 259. Preferably, the proximal ends 525 of the staple members 524 have barbs 526  
35 to improve the security of the attachment when the device is deployed.

          The anastomosis device 522 is prepared for use by mounting the device onto the distal end of a specially adapted

application instrument 527, as shown in Fig. 42B. The fastening flange 523 is mounted onto an anvil 528 attached to the distal end of the elongated shaft 531 of the application instrument 527. The staple members 524 are compressed inward against a conical holder 529 attached to the instrument 527 just proximal to the anvil 528. The staple members 524 are held in this compressed position by a cap 530 which is slidably mounted on the elongated shaft 531. The cap 530 moves distally to cover the sharpened, barbed ends 525 of the staple members 524 and to hold them against the conical holder 529. The application instrument 527 is then inserted through the lumen 249 of the graft vessel 254. This can be done by inserting the instrument through the graft vessel lumen 249 from the proximal to the distal end of the graft vessel 254, or it can be done by backloading the elongated shaft 531 of the instrument into the graft vessel lumen 249 from the distal end to the proximal end, whichever is most convenient in the case. The anvil 528 and holder 529 on the distal end of the application instrument 527 with the anastomosis device 522 attached is extended through the opening 267 into the lumen 256 of the target vessel 255.

Next, the distal end 259 of the graft vessel wall 254 is everted against the exterior surface 258 of the target vessel wall 255 with the graft vessel lumen 249 centered on the opening 267 in the target vessel wall 255. The cap 530 is withdrawn from the proximal ends 525 of the staple members 524, allowing the staple members 524 to spring outward to their uncompressed position shown by the phantom lines 524' in Fig. 42B. The application instrument 527 is then drawn in the proximal direction so that the staple members 524' pierce the target vessel wall 255 surrounding the opening 267 and the everted end 259 of the graft vessel 254.

The application instrument 527 has an annular staple former 532 which surrounds the outside of the graft vessel 254. Some slight pressure on the everted graft vessel wall 259 from the annular staple former 532 during the piercing step assists in piercing the staple members 524' through the graft vessel walls 259. Care should be taken not to apply too

much pressure with the staple former 532 at this point because the staple members 524' could be prematurely deformed before they have fully traversed the vessel walls. If desired, an annular surface made of a softer material, such as an elastomer, can be provided on the application instrument 527 to back up the vessel walls as the staple members 524' pierce through them.

Once the staple members 524' have fully traversed the target vessel wall 255 and the graft vessel wall 259, as shown in Fig. 42C, the staple former 532 is brought down with greater force while supporting the fastening flange 523 with the anvil 528. The staple members 524' are deformed outward, as shown by the phantom lines 524", so that the sharpened, barbed ends 525 pierce back through the everted graft vessel wall 259 and into the target vessel wall 255 to form a permanent attachment. To complete the anastomosis, the anvil 528 is withdrawn through the graft vessel lumen 249. As the anvil 528 passes through the wire ring fastening flange 523, it straightens out the wave-like ripples so that the wire ring 523 assumes its full uncompressed diameter, as shown in figure 42D. Alternatively, the wire ring fastening flange 523 can be made of a resilient material so that the flange 523 can be compressed and held in a rippled or folded position until it is released within the target vessel lumen 256, whereupon it will resume its full, expanded diameter. Another alternative construction would be to make the anastomosis device of a shape-memory alloy so that the wire ring fastening flange 523 can be compressed and inserted through the opening in the target vessel 267, whereupon it would be returned to its full expanded diameter by heating the device 522 to a temperature above the shape-memory transition temperature.

Figs. 43A-43B, 44A-44B, and 45A-45E show a complete system for creating an end-to-side vascular anastomosis using an anastomosis device 533 with a fastening flange 534 and a plurality of staple members 535 made of a highly resilient or superelastic metal. The system includes a specially adapted application instrument 536 for applying the anastomosis device 533. Fig. 43A shows a top view of the fastening flange 534 of

the anastomosis device 533. Fig. 43B shows the fastening flange 534 of Fig. 43A in cross section from the side. The fastening flange 534 is generally cylindrical in shape with a central orifice 537 of sufficient diameter to accommodate the external diameter of the graft vessel 254. The wall 538 of the fastening flange has a plurality of holes 539 extending from the proximal surface 540 of the flange to the distal surface 541 of the flange. Preferably there are an even number of holes 539, two for each of the staple members 535, which may number from four to twelve depending on the size of the vessels to be anastomosed. The illustrated embodiment has twelve holes 539 to accommodate six staple members 535. The holes 539 are preferably angled toward the central orifice 537 from the proximal end 540 to the distal end 541 so that they exit the wall 538 of the flange 534 at the juncture of the distal surface 541 of the flange and the internal surface of the central orifice 537. In the illustrative embodiment shown in Figs. 43A and 43B the holes 539 are angled at approximately 10 degrees to the longitudinal axis of the flange 534. Other angles are also possible, from -10 to +20 degrees from the longitudinal axis of the flange 534. The fastening flange 534 has a circumferential notch 542 on the exterior of the flange 534 close to the distal end 541 of the flange to aid in attachment of the graft vessel wall 254. There is also a circumferential ridge 543 around the exterior of the fastening flange 534 proximal to the notch 542 to assist in gripping the flange 534 for the operation of the application tool 536.

Figs. 44A and 44B show the staple member 535 of the anastomosis device 533 in a front view and a side view. The staple members 535 are preferably formed from wire made of a highly resilient biocompatible metal such as a spring-tempered alloy of stainless steel, titanium, or cobalt, or more preferably of a superelastic metal alloy, such as a nickel-titanium alloy. The wire preferably has a diameter between 0.006 and 0.025 inches, depending on the stiffness of the metal alloy chosen. Nickel-titanium wire with a diameter of 0.010 to 0.012 inches has been found to be very suitable for this application. The staple members 535 are roughly an

inverted U shape when viewed from the front with two attachment legs 544 joined together at their proximal ends by a crossbar 545, as shown in Fig. 44A. When viewed from the side as in Fig. 44B, the staple members 535 are roughly J-shaped with the distal ends 546 of the attachment legs 544 curving back toward the proximal end of the staple member 535. Each of the J-shaped hooks 547 ends in a short straight section 548 with a sharpened distal end 546 to easily penetrate the graft vessel 259 and target vessel 255 walls. The staple members 535 should be annealed or cold worked in the illustrated configuration, whichever treatment is most appropriate for the metal alloy chosen, so that the staple member has a permanent elastic memory which makes it return to the treated shape.

The holes 539 through the fastening flange 534 are sized so that there is a close sliding fit between the attachment legs 544 of the staple members 535 and the interior of the holes 539. The anastomosis device 533 is prepared for use by inserting the two attachment legs 544 of each staple member 535 into two adjacent holes 539 in the fastening flange 534, until the curved distal portion 547 of the attachment legs 544 are entirely within the holes 539. When inserting the staple members 535, they should be oriented so that the curve of the distal ends 547 of the attachment legs 544 will be biased outward from the central orifice 537 of the fastening flange 534 when extended distally from the holes 539 in the flange 534. Because of the close sliding fit, the interior walls of the holes 539 constrain the curved distal ends 547 of the attachment legs 544 in a straight position, as shown in Fig. 43B. The straight proximal portion 549 of the staple members 535 extend proximally from the proximal end 540 of the fastening flange 534 as shown.

The preparation of the anastomosis device 533 can also be accomplished using the shape-memory property of a nickel-titanium alloy. The staple members 535 would be formed as shown in Figs. 44A and 44B and annealed to create a shape-memory. The attachment legs 544 of the staple members 535 are then straightened by cold working them below the

transition temperature of the shape-memory alloy. In the straightened condition, the distal ends 547 of the attachment legs 544 are easily inserted into the holes 539 in the fastening flange 534. Care must be taken to orient the staple members 535 so that the curve of the distal ends 547 of the attachment legs 544 will be biased outward from the central orifice 537 of the fastening flange 534. Once all of the staple members 535 have been inserted into the holes 539 of the fastening flange 534, the entire anastomosis device 533 can be warmed above the transition temperature of the shape-memory alloy so that the distal ends 547 of the attachment legs 544 will try to return to their curved shape. Being constrained by the interior walls of the holes 539, the attachment legs 544 will remain straight, but they will have an elastic memory that will cause them to resume their curved shape when they are released from the confinement of the holes 539.

With the anastomosis device 533 thus prepared, it is ready to be inserted into the application instrument 536 which is shown in Figs. 45A-45E. The application instrument 536 consists of two separate, but interacting, mechanisms, a stapling mechanism 550 and a punching mechanism 551. The punching mechanism 551 is sized to be slidably received within an internal lumen 552 of the stapling mechanism 550. Most of the parts of the application instrument 536, unless otherwise specified, are preferably made of a high-strength, dimensionally stable polymer material, such as acetal, ABS, HDPE, PTFE, etc. Alternatively, the application instrument 536 could be made from stainless, steel, titanium or other metals, if desired.

The stapling mechanism 550 has a generally cylindrical holder 553 which has a proximal end 554 and a distal end 555. An internal lumen 556 extends from the proximal end 554 to the distal end 555. The distal end 555 of the holder 553 is adapted to hold the fastening flange 534 of the anastomosis device 533. A through hole 557 in the distal end of the holder 553 is sized to be a light press fit around the proximal end 540 of the fastening flange 534. A

counterbore 558 on the distal end of the through hole 557 fits the circumferential ridge 543 of the fastening flange 534 to axially locate the fastening flange 534 with respect to the holder 553. A staple driver 559, which is generally tubular in shape, is slidably received within the internal lumen 556 in the holder 553. The staple driver 559 has a T-shaped handle 560 attached to its proximal end for operating the stapling mechanism 550. The proximal end of the staple driver 559 has a short tubular extension 561 with a circumferential groove 562 around the exterior of the tubular extension 561. The distal end has an annular staple driving surface 563.

To insert the anastomosis device 533 into the distal end of the stapling mechanism 550, the proximal ends 549 of the staple members 535 must be flexed slightly toward the central axis of the fastening flange 534 so that they will all fit through the through hole 557 on the distal end of the holder 553. Once the proximal ends 549 of the staple members 535 have been inserted, the proximal end of the fastening flange 540 is inserted into the through hole 557 with the circumferential ridge 543 seated into the counterbore 558.

The stapling mechanism 550 is now ready for attachment of the graft vessel 254 to the fastening flange 534. To begin, the graft vessel 254 is passed through the internal lumen 552 of the holder 553 and the staple driver 559. This can be done by tying a suture around one end of the graft vessel 254, passing the suture through the stapling mechanism 550 and drawing the graft vessel 254 through. Alternatively, an elongated hook or grasping instrument can be inserted through the lumen 552 of the stapling mechanism 550 to draw the graft vessel 254 through. The distal end 259 of the graft vessel 254 is then everted over the distal end 541 of the fastening flange 534. If desired, a loop of suture 564 can be tied around the everted end 259 of the graft vessel 254 at the location of the circumferential notch or groove 542 to secure the graft 259 to the fastening flange 534. The proximal end 565 of the graft vessel 254 can also be everted and temporarily attached with a loop of suture to the proximal

extension 561 of the staple driver 559 to make the graft vessel 254 easier to handle.

At this point, the vessel punch mechanism 551 should be inserted into the stapling mechanism 550 through the lumen 249 of the graft vessel 254. The vessel punch mechanism 551 consists of a housing 566, a cutter 567, an anvil 568, a clamp 569, a clamp knob 570 and a punch knob 571. The housing 566 is generally cylindrical in shape. There are two inner chambers 572, 573 in the housing which are separated by an internal wall 574. The distal chamber 572 is sized to have a light press fit over the holder 553 of the stapling mechanism 550. A pair of set screws 575 in the side wall 576 of the distal chamber 572 are provided to secure the housing 566 to the holder 553. The side wall 576 of the distal chamber 572 has pair of opposing open-ended slots 577 that are sized to fit over the T-shaped handle 560 of the staple driver 559 and allow the handle 560 to move axially within the slots 577. The proximal chamber 573 has an internal thread 579 that matches an external thread 579 on the clamp knob 570. A counterbored hole 580 through the internal wall 574 connects the proximal 573 and distal 572 chambers.

The cutter 567 of the vessel punch mechanism 551 is a long slender tubular member which is preferably made of a hardenable alloy of stainless steel. The distal end 581 of the cutter 567 is slightly enlarged with respect to the shaft 582 of the cutter 567, and there is a counterbore 583 within the enlarged distal end 581. The distal edge of the cutter 567 has a sharp, beveled cutting edge 584. Preferably, at least the cutting edge 584 of the tubular cutter 567 is hardened. The proximal end of the cutter shaft 582 has a snug press fit into the counter hole 580 through the internal wall 574 of the housing 566. The punch mechanism 551 also includes a clamp 569. The clamp 569 has a long tubular shaft 585 which is sized to be slidably received within the internal lumen 586 of the cutter shaft 582. An enlarged head 587 on the distal end of the shaft 585 is sized to fit within the counterbore 583 in the distal end of the cutter 567. The distal end of the enlarged head 587 has an annular clamping surface 588.

The proximal end of the clamp shaft 585 is inserted into the cutter 567 and glued or otherwise fastened to the clamp knob 570 which is threaded into the proximal chamber 573 of the housing 566. The anvil 568 of the punch mechanism 551 is preferably made of stainless steel. The anvil 568 has an elongated shaft 589 that has a sliding fit with the internal lumen 590 of the clamp 569. An enlarged head 591 on the distal end of the shaft 589 is sized to fit within the counterbored distal end 583 of the cutter with a very close clearance between the head of the anvil 591 and the cutter 567. The proximal end of the shaft 589 is threaded to attach it to the punch knob 571. The punch knob 571 has a distal extension 592 which is threaded to fit into a threaded hole 593 on the proximal end of the clamp knob 570.

When the clamp knob 570 is rotated with respect to the housing 566, the clamp 569 is advanced proximally or distally with respect to the cutter 567. In its farthest distal position, the clamping surface 588 of the clamp 569 is just distal to the cutting edge 584 of the tubular cutter 567. When the punch knob 571 is rotated with respect to the clamp knob 570, the anvil 568 is advanced proximally or distally with respect to the clamp 569. By moving the anvil 568 proximally with respect to the clamp 569 when the clamp is in its farthest distal position, the tissue of the target vessel wall can be clamped between the clamp and the anvil. When the clamp knob 255 and the punch knob 571 are rotated in unison, the anvil 568 and the clamp 569 can be withdrawn into the tubular cutter 567 to effect the cutting action of the punch mechanism 551. Preferably, the clamp 569, the anvil 568 and the tubular cutter 567 are keyed to one another or otherwise rotationally fixed so that they move axially with respect to one another without relative rotation.

The punch mechanism 551, as it has just been described, is inserted into the stapling mechanism 550 through the lumen 249 of the graft vessel 254. The clamp 569 of the punch mechanism 551 should be advanced to its farthest distal position before inserting the punch 551 through the graft vessel 254 to avoid damaging the interior wall of the graft

vessel 254 with the cutter 567 as it passes through. The set screws 575 in the housing 566 of the punch mechanism 551 are screwed into corresponding holes 594 in the holder 553 of the stapling mechanism 550 to secure the two interacting mechanisms together. The graft vessel 254 occupies an annular space 595 between the punch mechanism 551 and the interior surface of the stapling mechanism 550. Thus assembled, the anastomosis system, which includes the anastomosis device 533 attached to the graft vessel 254 and the application instrument 536, is prepared to perform an end-to-side anastomosis between the graft vessel 254 and a target vessel 255.

The operation of the application instrument 536 is illustrated in Figs. 45A-45E. A slit 596 is made in the wall of the target vessel 255 with a scalpel or other sharp instrument. If it has not been done already, the clamp 569 of the punch mechanism 551 is advanced distally by turning the clamp knob 570 until the clamp surface 588 extends slightly beyond the cutting edge 584 of the cutter 567, and the anvil 568 of the punch mechanism 551 is advanced distally by turning the punch knob 571 until the anvil head 591 extends distally from the application instrument 536. The anvil head 591 of the punch mechanism 551 is inserted through the slit 596 into the lumen 256 of the target vessel 255, and the distal edge 541 of the fastening flange 534 with the everted end 259 of the graft vessel 254 attached is approximated to the exterior surface 258 of the target vessel 255, as shown in Fig. 45A. The target vessel wall 255 is then clamped by the punch mechanism 551 by turning the punch knob 571 to move the anvil head 591 proximally until the target vessel wall 255 is firmly gripped between the anvil head 591 and the clamp surface 588, as shown in Fig. 45B. The clamp feature of the punch mechanism 551 prevents the cutter 567 from prematurely cutting through the wall of the target vessel 255 and it provides a firm support to the target vessel wall 255 for the stapling step which follows.

If the anastomosis system is being used to create a proximal anastomosis between a graft vessel and the aorta

during a CABG procedure, the clamping feature provides an additional benefit at this point in the procedure. In order to reduce the crossclamp time that the patient is subjected to, many cardiac surgeons prefer to perform the proximal anastomosis while the patient's heart is still beating. This requires isolating a portion of the aortic wall with a nonoccluding side-biting clamp to prevent excessive bleeding from the opening formed in the aorta. This has a number of disadvantages: 1) even a nonoccluding side-biting clamp presents additional resistance to aortic blood flow, possibly reducing cardiac output which may already be low, 2) the side-biting clamp tends to distort the aortic wall, making it harder to create a neat anastomosis, 3) conventional side-biting clamps are difficult to apply in a closed-chest or port-access thoracoscopic CABG procedure, and 4) side-biting clamps may break atherosclerotic tissue loose from the inner wall of the aorta, possibly causing strokes or other complications. The clamping feature reduces the need for the side-biting clamp by clamping directly to the aortic wall around the slit made by the scalpel for inserting the anvil. This creates a fluid-tight seal preventing bleeding through the aortotomy opening, so that the side-biting clamp can be released and removed from the site. It is also possible to avoid the need for the side-biting clamp entirely by quickly inserting the anvil head 591 of the punch mechanism 551 and tightening the clamp 569 immediately after creating the aortotomy slit before significant blood loss can occur. If the head of the anvil 591 were made with a blade or trocar extending from its distal surface, the device 536 could pierce and dilate an opening in the aorta wall in the same motion as inserting the anvil 591 through the opening, potentially saving time and blood loss.

In the stapling step, the staple driver 559 is advanced distally by pressing on the T-shaped handle 560, as shown by arrows 597 in Fig. 45C. This causes the distal end 563 of the staple driver 559 to press against the crossbars 545 of the staple members 535 and forces the attachment legs 544 to exit through the holes 539 in the distal end 541 of the

fastening flange 534. As the attachment legs 544 emerge from the holes 539, the sharpened distal ends 546 of the attachment legs 544 pierce the graft vessel wall 259 and the short straight section 548 traverses the graft vessel wall 259 in a linear path. Optionally, the staples 535 can be advanced through the graft vessel wall 259 before the graft vessel 259 is approximated to the target vessel 255 so that the surgeon can verify that all of the staple attachment legs 544 have properly pierced the everted graft vessel wall 259. The sharpened distal ends 546 of the attachment legs 544 then pierce the target vessel wall 255. The clamping feature 569 of the punch mechanism 551 supports the target vessel wall 255 and keeps it closely approximated to the everted end 259 of the graft vessel 254 as the staple members 535 penetrate it. As the attachment legs 544 penetrate the target vessel wall 255, the curved sections 547 of the attachment legs 544 emerge from the confinement of the holes 539 in the fastening flange 534 and the elastic memory of the unrestrained curve causes the attachment legs 544 to take a curved path outwardly from the central orifice 537 through the target vessel wall 255. The distal ends 547 of the attachment legs 544 resume their J shape, as shown in Fig. 45C, firmly attaching the fastening flange 534 and the everted graft vessel 259 to the exterior surface 258 of the target vessel 255.

Once the fastening flange 534 and the graft vessel 254 are attached, an opening 267 is made in the target vessel wall 255 by turning the clamp knob 570 and punch knob 571 in unison to withdraw the anvil 568 and the clamp 569, with the target vessel wall 255 gripped between them, into the tubular cutter 567, as shown in Fig. 45D. This action shears off a small, circular portion of the target vessel wall 255 to form a fluid communication between the lumen 256 of the target vessel 255 and the lumen 249 of the graft vessel 254. To complete the anastomosis, the fastening flange 534 is released from the holder 553 and the punch mechanism 551 and the entire application instrument 536 are withdrawn, as shown in Fig. 45E.

Figs. 46A-46D illustrate a second embodiment of the anastomosis system using an anastomosis device 600 with an inner fastening flange 601, an outer flange 602 and staple members 603 made of a superelastic nickel-titanium alloy. The system includes a stapling mechanism 604 for attaching the anastomosis device 600 to the wall of the target vessel 255 through a previously made opening 267. The anastomosis device 600 has a fastening flange 605, which is shown in top view in Fig. 46C and in side cross section views in Figs. 46A and 46B. The fastening flange 605 includes a tubular body 606 which has an internal lumen 607 of sufficient diameter to accommodate the external diameter of the graft vessel 254. Attached to the distal end of the tubular body 606 is an inner flange 601 over which the free end 259 of the graft vessel 254 will be everted. On the proximal end 610 of the tubular body 606 are three radially extending lugs 608, which facilitate grasping the anastomosis device 600 while performing the anastomosis. The exterior of the tubular body 606 has an external step 609 so that it is slightly larger in diameter at its proximal end 610 than at its distal end 611. The interior of the tubular body 606 has an internal step 612 so that the internal diameter of the tubular body is slightly smaller at the distal end 610 than at the proximal end 611. A plurality of holes 613 pass through the fastening flange 605 from the internal step 612 to the distal surface 611 of the inner flange 601. The holes 613 are arranged in pairs, six pairs in this illustrative example, to accommodate a like number of staple members 603.

An outer flange 602 is concentrically located on the tubular body 606. The outer flange 602 is attached to the tubular body 606 by a self-locking ring washer 614 which has inclined lugs 615 which allow the ring washer 614 to slide distally with respect to the tubular body 606, but which prevent it from sliding proximally. The ring washer 614 can be made integrally with the outer flange 602 or a separate sheet metal ring washer 614 can be attached to the outer flange 602, as illustrated. The internal orifice 616 of the ring washer 614 and the outer flange 602 is made with three

wide slots 617 between the inclined lugs 615 to allow them to be placed onto the tubular body 606 over the lugs 615 which extend from the proximal end 610 of the tubular body 606. The outer flange 602 has a distal surface 618 which is slightly concave. The peripheral edge 619 of the outer flange 602 has six notches 620 cut into it which coincide with the location of the distal ends 621 of the staple members 603 after they are deployed, as shown in Fig. 46C.

The staple members 603 are generally an inverted U shape when viewed from the front as in Fig. 46D. Two attachment legs 622 are joined together at their proximal ends by a crossbar 623. Viewed from the side as in Fig. 46B, the staple members are somewhat J-shaped with the sharpened distal ends 624 curving back in the proximal direction. The staple members 603 are preferably formed from wire made of a highly resilient biocompatible metal such as a spring-tempered alloy of stainless steel, titanium, or cobalt, or more preferably of a superelastic metal alloy, such as a nickel-titanium alloy.

For clarity only the distal end of the stapling mechanism 604 has been shown in Fig. 46A. Suitable handle means are provided at the proximal end for actuating the stapling mechanism 604. The stapling mechanism 604 has an outer sleeve 625, which is a tubular member having three L-shaped fingers 626 extending from its distal end that grasp the radially extending lugs 615 on the proximal end of the tubular body 606 like a bayonet connector. The clamp sleeve 627 is a tubular member which slides telescopically over the exterior of the outer sleeve 625. A staple guide 628 resides within the outer sleeve 625. The staple guide 628 is a tubular member having a plurality of slots 629, equal to the number of staple members 603 in the anastomosis device, extending through the wall from the proximal end to the distal end of the guide 628. The slots 629 in the guide 628 are sized to fit the staple members 603 therein and to constrain the J-shaped attachment legs 622 of the staple members 603 in a straight position prior to deployment, as shown in Fig. 46A. The staple guide 628 can be made by cutting a plurality of slots 629 through the wall of the tubular member with

electrical discharge machining, or the staple guide 628 can be made from two closely fitting concentric tubes by cutting slots like splines in the external surface of the inner tube and sliding the outer tube over it to close the slots. The staple driver 630 is a tubular member which is slidably received within the outer sleeve 625. A plurality of fingers 631 extend from the distal end of the staple driver 630. The fingers 631 of the staple driver 630 are sized to be slidably received within the slots 629 of the staple guide 628.

The anastomosis device 600 is prepared by inserting the staple members 603 into the slots 629 in the staple guide 628 in the stapling mechanism 604. The staple guide 628 holds the staple members 603 in a straightened position within the stapling mechanism 604. The fastening flange 605 is inserted into the stapling mechanism 604 and the radially extending lugs 608 are grasped by the L-shaped fingers 626 of the outer sleeve 625. The staple holes 613 through the tubular body 606 are carefully aligned with the distal ends 621 of the staple members 603 and the staple driver 630 is advanced slightly to start the staple members 603 into the holes 613. The anastomosis device 600 is now prepared to perform an end-to-side anastomosis between a graft vessel 254 and the wall of a target vessel 255 as follows.

To begin, the graft vessel 254 is inserted through the central lumen 607 of the fastening flange 605 and the internal lumen 632 of the stapling mechanism 604 by drawing it through with a suture or an elongated grasping instrument. The distal end 259 of the graft vessel 254 is then everted over the inner flange 601 on the distal end 611 of the fastening flange 605. The inner flange 601 with the everted end 259 of the graft vessel 254 attached is inserted through an opening 267 in the target vessel wall 255 that has previously been made using an aortic punch or similar instrument. The staple driver 630 is advanced distally, causing the sharpened ends 621 of the staple members 603 to pierce the everted wall 259 of the graft vessel 254 and enter the lumen 256 of the target vessel 256. As the staple members 603 emerge from the distal end 611 of the fastening flange

605, the attachment legs 622 resume their J-shaped curve and penetrate the interior surface 257 of the target vessel wall 255, as shown in Fig. 46D. Once the staple members 603 are completely deployed, the clamp sleeve 627 is advanced distally with respect to the outer sleeve 625, which forces the outer flange 602 to move in the distal direction with respect to the tubular body 606. As the outer flange 602 moves distally, the inner flange 601 and the target vessel wall 255 are pulled into the concave distal surface 618 of the outer flange 602 to form a smooth, hemodynamically efficient connection between the lumen 256 of the target vessel 255 and the lumen 249 of the graft vessel 254. The stapling mechanism 604 is now removed by rotating the outer sleeve 625 to release its grasp on the tubular body 606 and withdrawing the entire stapling mechanism 604. It should be noted that the embodiment of Fig. 46, like the embodiment of Fig. 43, could optionally be manufactured without an inner flange 601, whereby the inner wall 257 of the target vessel 255 is supported by the staple members 603 themselves.

Figs. 47A-47B, 48A-48B, and 49A-49C show an anastomosis staple device 635 which combines a plurality of precurved inner staple members 636 of a highly resilient material with a plurality of deformable outer attachment legs 637. Figs. 47A-47B show a top view and a side cross section view of the anastomosis staple in an undeployed state. Figs. 47A-47B show a top view and a side cross section view of the anastomosis staple in a deployed state. Figs. 49A-49C show the sequence of operations for deploying the anastomosis staple device. As shown in Figs. 47A-47C, the device 635 has a ring-shaped bushing 638 with an internal diameter 639 of sufficient size to accommodate the exterior diameter of the graft vessel 254. A plurality of deformable attachment legs 637, six in this exemplary embodiment, are attached to the proximal end of the ring-shaped bushing 638. The deformable attachment legs 637 are preferably made of a metal which can be plastically deformed and which will maintain its final deformed shape, such as stainless steel or a titanium alloy. The attachment legs 637 can be machined integrally with the

ring-shaped bushing 638 as shown, or the attachment legs 637 can be made separately, for instance by stamping, electrical discharge machining or die cutting a ring of attachment legs 637 from sheet metal, and fastening the attachment legs 637 to the ring-shaped bushing 638. The attachment legs 637 are typically 0.012 inches thick, 0.040 inches wide and 0.230 inches long. The thickness and width of the attachment legs can vary somewhat depending on the stiffness of the material chosen for the attachment legs 637. It may be desirable to radius the edges of the attachment legs 637 or to make the attachment legs 637 round in cross section in order to reduce the potential for initiating cracks or tears in the target vessel wall 255. The length of the attachment legs 637 can be varied to accommodate different wall thicknesses of the graft vessels 254 and target vessels 255 to be attached.

The attachment legs 637 are typically formed flat, then bent or stamped into a curved configuration as shown in Figs. 47B. The distal portion 640 of each attachment leg 637 is curved in a circular arc whose center coincides approximately with the point of attachment 641 between the attachment leg 637 and the ring-shaped bushing 638. The attachment point 641 serves as the bending fulcrum for the attachment legs 637 when they are deformed during the anastomosis procedure. The intermediate portion 642 of the attachment legs 637 can be left relatively straight, or an intermediate curve 642 can be formed in the attachment legs 637, as shown in Fig. 47B. The distal ends 643 of the attachment legs 637 are sharpened so that they will easily penetrate the target vessel walls 255.

The ring-shaped bushing 638 has a distal surface 644 over which the end 259 of the graft vessel 254 will be everted. The distal end 644 of the ring-shaped bushing 638 is flared out slightly to provide a more secure attachment of the everted end 259 of the graft vessel 254 to the bushing 638. There are a plurality of axial holes 645 in the wall of the ring-shaped bushing 638 which communicate with the distal surface 644 of the bushing 638. The holes 645 are sized to have a close sliding clearance with the legs 646 of the inner

staple members 636. Preferably, the axial holes 645 are arranged in pairs to accommodate both legs of U-shaped inner staple members 636. As shown in Fig. 47A, the currently preferred embodiment has six pairs of axial holes 645 for six U-shaped inner staple members 636. The axial holes 645 are angled outward slightly, typically by about 10 degrees, from the central axis of the ring-shaped bushing 638. Angling the axial holes 645 outward tends to reduce the distance from the distal surface 644 of the bushing 638 to the bottom of the curve of the staple members 636 once the staple members 636 have been deployed. There are also a plurality of transverse holes 647 through the wall of the ring-shaped bushing 638 to facilitate gripping the bushing 638 with the staple application instrument 648.

The staple members 636 are generally an inverted U shape when viewed from the front as in Fig. 47A. Two staple legs 646 are joined together at their proximal ends by a crossbar 649. Viewed from the side as in Fig. 48B, the deployed staple members 636 are somewhat J-shaped with the sharpened distal ends 650 curving back approximately 180 degrees in the proximal direction. The staple members 636 are preferably formed from wire made of a highly resilient biocompatible metal such as a spring-tempered alloy of stainless steel, titanium, or cobalt, or more preferably of a superelastic metal alloy, such as a nickel-titanium alloy. The anastomosis staple device 635 is prepared for use by inserting the curved distal ends 651 of the J-shaped staples into the axial holes 645 in the ring-shaped bushing 638. The internal walls of the axial holes 645 hold the curved ends 651 of the staple members 636 in a straightened position within the ring-shaped bushing 638.

The anastomosis staple of Figs. 47A-47B and 48A-48B is part of a complete anastomosis system which includes a specialized staple application instrument 648 for performing the anastomosis procedure. The staple application instrument 648 is shown in Figs. 50A-50B. As seen in Fig. 50B, the instrument 648 has a gripper 652 which is adapted to hold the ring-shaped bushing 638 of the staple device. The gripper 652

is a generally tubular member that has a plurality of gripping fingers 653 extending axially from its distal end. Each of the gripping fingers 653 has an inwardly turned distal tip 654 which is sized to fit into one of the transverse holes 647 in the ring-shaped bushing 638. The gripping fingers 653 are spring-biased outward. A combination gripper actuator and outer attachment leg driver 655 is slidably received on the exterior of the gripper shaft 656. The actuator/driver 655 is generally tubular in shape, having a lumen 657 with a close sliding fit over the exterior of the gripper 652 and a radiused annular staple driving surface 658 on its distal end. When the actuator/driver 655 is slid distally over the exterior of the gripping fingers 653, the outwardly biased fingers 653 are pressed inward so that they grip the ring-shaped bushing 638 by engaging the transverse holes 647.

An inner staple driver 659 is slidably received within the inner lumen 661 of the tubular shaft 656 of the gripper 652. The inner staple driver 659 has an annular staple driving surface 660 on its distal end. The inner staple driver 659 has an internal lumen 662 that can accommodate the graft vessel 254 during the anastomosis procedure. The gripper 652, the actuator/driver 655 and the inner staple driver 659 are held together by a pair of alignment pins 663 which are threaded into the wall of the actuator/driver 655. The gripper shaft 656 has a pair of opposing axial slots 664 that allow it to slide axially with respect to the actuator/driver 655. The inner staple driver 659 has a pair of opposing L-shaped slots 665 oriented to allow the inner staple driver 659 to slide axially with respect to the gripper 652 and the actuator/driver 655. The inner staple driver 659 can be moved to a locked position to prevent premature activation of the inner staples 636 by withdrawing it distally and rotating it so that the alignment pins 663 enter the L-shaped portion 666 of the slots 665.

In preparation for the anastomosis procedure, the proximal end of the ring-shaped bushing 638, with the proximal ends of the inner staples 636 extending from it, is inserted into the gripper 652 with the transverse holes 647 aligned

with the ends 654 of the gripping fingers 653. The inner staple driver 659 should be withdrawn to the locked position before the staple device 648 is inserted. The actuator/driver 655 is advanced distally, causing the ends 654 of the gripping fingers 653 to flex inward and engage the transverse holes 647 in the ring-shaped bushing 638. The actuator driver 655 can be advanced distally until it rests against, but does not deform, the attachment leg 637 of the staple device 635.

At this point the graft vessel 254 is passed through the internal lumen 662 of the staple applying instrument 648 until a short length of the graft 254 extends from the distal end of the instrument 635. The end 259 of the graft 254 is then everted over the distal surface 644 of the ring-shaped bushing 638. If desired, a loop of suture can be tied around the everted end 259 of the graft vessel 254 to secure it to the bushing 638. The staple instrument 635, with the everted end 259 of the graft vessel 254 attached, is approximated to the exterior surface 258 of the target vessel 255 where an opening 267 in the target vessel wall 255 has previously been made with a vessel punch or similar instrument. If the anastomosis is part of a port-access CABG procedure, the instrument 635 is inserted into the chest of the patient through an access port made in one of the intercostal spaces.

The ring-shaped bushing 638 is inserted into the opening 267 in the target vessel wall 255 to approximate the intimal surface on the everted end 259 of the graft vessel 254 with the intimal surface 257 of the target vessel 255, as shown in Fig. 49A. Preferably, the opening 267 in the wall of the target vessel 255 is made slightly smaller than the outer diameter of the ring-shaped bushing 638 so that there is some compression around the bushing 638 which helps to seal the anastomosis against leakage. The inner staple driver 659 is rotated to release it from the locked position and advanced distally to drive the inner staple members 636 through the everted wall 259 of the graft vessel 254. As the staple members 636 exit the axial holes 645 in the bushing 638, they resume their J-shaped curve 651 so that they curve back distally and penetrate the interior surface 257 of the target

vessel wall 255, as shown in Fig. 49B. After the inner staple members 636 have been deployed, a light tension is exerted on the staple applying instrument 648 to make sure that the inner staple members 636 are well seated and the actuator/driver 655 is advanced distally to deform the outer attachment legs 637. The sharpened distal ends 643 of the attachment legs 637 penetrate the exterior 258 of the target vessel wall 255 in a circular arc, gathering the tissue and compressing it against the exterior of the ring-shaped bushing 638 and the everted edge 259 of the graft vessel 254 to form a leak-proof anastomotic seal, as shown in Fig. 49C. The actuator/driver 655 is withdrawn in the proximal direction, thereby releasing the ring-shaped bushing 638 from the gripper 652, and the entire staple applying instrument 648 is withdrawn from the anastomosis site.

Fig. 51 shows an additional feature which can be used with any of the anastomosis devices described above. This feature is a combination strain relief and compliance mismatch transition sleeve 667. One of the current theories about long-term patency and the causes of restenosis in bypass grafts proposes that the mismatch in vessel compliance between the target vessels, which include the aorta and the coronary arteries, and the graft vessel, typically a saphenous vein, can contribute to the development of intimal hyperplasia, stenosis and occlusion in the graft vessel, especially at the anastomosis where the compliance mismatch is most apparent. Joining a highly compliant vessel, such as a saphenous vein, to a relatively noncompliant vessel, like the aortic wall, places extra strain on the vessels and on the anastomosis. Another cause for mismatched compliance at an anastomosis site is the joining of a compliant blood vessel with a highly noncompliant artificial graft vessel. Additionally, turbulence in the blood flow at the anastomosis site may exacerbate the problem, accelerating the stenosis process. It is preferable that all of the vessels be equally compliant or at least that there is a gradual transition in compliance from one vessel to another. As such, it would be desirable to provide the anastomosis devices with a means to create a

gradual transition in compliance between the vessels at the anastomosis site.

Another concern in anastomosis procedures is to create a gradual curve in the graft vessel leading away from the anastomosis site. This is sometimes necessary because the most convenient angle for attaching the graft vessel to the target vessel does not match the desired path for the graft vessel away from the anastomosis. For instance, in CABG surgery the desired path for the graft vessel is often parallel to the ascending aorta, however the graft vessel must be joined to the ascending aorta at some angle in order to create the anastomosis. Creating a gradual curve leading away from the anastomosis site to avoid kinking or narrowing of the graft vessel lumen is sometimes problematic. This is especially true when the graft vessel is joined at right angles to the ascending aorta. It would be desirable therefore to provide the anastomosis devices with a reliable means to create a gradual curve in the graft vessel leading away from the anastomosis site.

The combination strain relief and compliance mismatch transition sleeve 667 is a flexible tubular member 668 which can be appended to the proximal end of the anastomosis device 669 to support the graft vessel 254 leading away from the anastomosis site. The flexible tubular member 668 may have any or all of gradually decreasing stiffness, increasing compliance and increasing diameter as it extends proximally from the anastomosis device 669. This will give the graft vessel 254 a gradual curve, a gradual change in its radial compliance, and a gradual change in diameter from the constrained diameter within the anastomosis device 669 to an unconstrained diameter some distance from the device 669.

The strain relief sleeve 667 can be made in any one of several possible constructions, including braided wire or monofilament, a wire or plastic coil, a solid polymer tube or a composite construction, such as a wire coil embedded in a polymer wall. The strain relief sleeve 667 may also be made of a soft, stretchy, biocompatible polymer, such as polyurethane, silicone, or Gortex (expanded PTFE).

Fig. 52 shows a device 670 for isolating a portion of the target vessel lumen 256 to facilitate performing an anastomosis using any of the devices and techniques described herein. The isolation device 670 may be used as an alternative to the side-biting clamp described above for use in the proximal anastomosis procedure during CABG surgery. The side-biting clamp is used in CABG surgery to isolate a portion of the aortic wall so that the proximal anastomosis can be performed while the heart is still beating without excessive bleeding at the anastomosis site. Placing a side-biting clamp thoroscopically during port-access CABG surgery may prove problematic. A perfusion endoaortic clamp catheter 670, as shown in Fig. 52, performs the same functions as the side-biting clamp with a percutaneously placed catheter. The catheter 670 has a first doughnut-shaped balloon 671 and a second doughnut-shaped balloon 672 which are interconnected by a large-bore perfusion tube 673. The balloons 671 672 and the perfusion tube 673 are mounted on the distal end of an elongated catheter shaft 674. The balloons 671, 672 and the perfusion tube 673 are preferably made of a semi-elastic polyurethane material so that it can be collapsed for percutaneous entry and so it will resume the appropriate shape when they are deployed. The catheter shaft 674 may have a single inflation lumen 675 which connects to both balloons 671, 672 or separate inflation lumens connected to each balloon. If desired, the catheter 670 may also be provided with a flushing lumen which connects to a flushing port located on the exterior of the perfusion tube 673 between the balloons 671, 672 for flushing the anastomosis site 678 with clear saline to improve visibility.

In operation, the balloons 671, 672 and the perfusion tube 673 are introduced percutaneously into a peripheral artery, such as the femoral artery and advance into the ascending aorta 676, preferably under fluoroscopic visualization. When the surgeon is prepared to make the aortotomy incision to start the proximal anastomosis procedure, the first and second balloons 671, 672 are inflated, isolating the portions of the aortic wall 677

between the two balloons 671, 672 from the blood flow in the aorta. Blood continues to flow through the large-bore perfusion tube 673, supplying the rest of the body with blood. With the aortic wall 677 isolated, the aortotomy incision can be made at the anastomosis site 678 and the anastomosis completed by any of the methods described in the specification. After the anastomosis is complete, the balloons 671, 672 are deflated and the catheter is withdrawn from the aorta 676.

This catheter approach has certain advantages over the use of a side-biting clamp. First, it isolates a larger portion of the aortic wall so that the surgeon has more choice in the placement of the anastomotic sites. Second, because it isolates a larger portion of the aortic wall it also allows multiple anastomoses to be made to the aorta without having to move the clamp. Third, it does not distort the wall of the aorta as the side-biting clamp does. This may allow more accurate placement of the anastomotic sites and more effective attachment of the anastomosis devices and therefore reduced leakage of the anastomoses.

A second, smaller scale version of a similar catheter device 679 is shown in Fig. 53 for isolating a section of a coronary artery 682 while performing a distal anastomosis. This device would allow the section of the coronary artery 682 close to the anastomosis to be isolated from the blood flow without blocking blood flow to vital myocardium downstream of the anastomosis site. The availability of rapid and reliable anastomosis devices, such as those described herein, could open the door to performing CABG surgery on patients whose hearts are still beating, with no need at all for cardioplegic arrest. The rapidity of the anastomosis procedure using these devices will minimize the interference from the wall motion of the beating heart that makes hand sutured anastomoses problematic. However, two other obstacles remain: 1) excessive bleeding at the anastomotic site when the coronary artery is incised, and 2) temporary ischemia of the myocardial tissue downstream of the anastomosis site. The catheter 679 in Fig. 53 solves both of

these potential problems. The distal end of the catheter has a distal balloon 680 and a proximal balloon 681 separated by a few centimeters distance along the catheter shaft 683. The balloons 680, 681 may be elastic balloons made of latex, polyurethane or silicone, or they may be inelastic balloons made of polyethylene, polyester or polyamide. The catheter shaft 683 may have a single inflation lumen 648 which connects to both balloons 680, 681 or separate inflation lumens connected to each balloon. If desired, the catheter 679 may also be provided with a flushing lumen which connects to a flushing port located on the catheter shaft 683 between the balloons 680, 681 for flushing the anastomosis site 690 with clear saline to improve visibility. In addition, the catheter shaft 683 has a perfusion lumen 685 for blood flow through the catheter 679. The perfusion lumen 685 has one or more inflow ports 686 on the catheter shaft 683 proximal to both of the balloons 680, 681 and at least one outflow port 687 at the end of the catheter 679, distal to both of the balloons 680, 681.

In operation, the catheter 679 is introduced into the coronary artery 682 through a coronary guiding catheter 688 which is preferably introduced percutaneously from the femoral or brachial artery. The distal balloon 680 is advanced past the stenosis 689 in the artery 682, preferably under fluoroscopic visualization, and placed distal to the desired anastomosis site 690. The proximal balloon 681 is placed proximal to the desired anastomosis site 690 at a point which may be proximal or distal to the stenosis 689. The inflow ports 686 of the perfusion lumen 685, however, should be located proximal to the stenosis 689. The proximal 681 and distal 680 balloons are inflated to isolate the area between them from the blood flow through the coronary artery 682. Blood continues to flow into the artery distal to the catheter 679 through the perfusion lumen 685. The distal anastomosis procedure can now be performed on the isolated section of the coronary artery. When the anastomosis is complete, the balloons 680, 681 are deflated and the catheter 679 is withdrawn.

A third catheter device 691 is shown in Fig. 54. This catheter device 691 is configured to be delivered to the anastomosis site through the lumen 249 of the graft vessel 254 which has a number of potential advantages. First, the device  
5 691 can be used without the need for a femoral or brachial artery puncture or a coronary guiding catheter to deliver the catheter 691 into the coronary arteries 682. Second, the catheter 691 can be deployed under direct or endoscopic  
10 visualization by the surgeon without the need for fluoroscopic imaging. Third, the T-shaped configuration of the catheter 691 can help to facilitate approximation of the graft vessel 254 and the target vessel 255 during the anastomosis procedure.

The catheter 691 has a proximal catheter body 692  
15 connected to a T-shaped distal portion 693. The T-shaped distal portion 693 has two distal ends 694, 695, each having an inflatable balloon 696, 697 at its distal extremity. The balloons 696, 697 are each connected to one or more inflation  
20 lumens 698 that terminate in a luer fitting at the proximal extremity of the proximal catheter body 692. A perfusion lumen 699 connects a separate luer fitting at the proximal extremity of the proximal catheter body 692 to the extremities  
of both distal ends 694, 695 of the catheter 691, distal to the inflatable balloons 696, 697.

25 In operation, the T-shaped distal end 693 of the catheter is passed through the lumen 249 of the graft vessel 254 with the balloons 696, 697 deflated. An incision 700 is made in the wall of the coronary artery 682 or other vessel at the desired anastomosis site and both distal ends 694, 695 of  
30 catheter 691 are introduced into the coronary artery 682 through the incision 700. One distal end 695 of the catheter 691 is directed upstream of the anastomosis site and the other distal end 694 is directed downstream of the anastomosis site. Both of the balloons 696, 697 are inflated to isolate the  
35 portion of the coronary artery 682 between the balloons 696, 697 from the blood flow in the artery. Two modes of perfusion are possible with the catheter 691. If the upstream end 695 of the distal portion 693 of the catheter 691 receives enough

blood flow, the blood will pass through the perfusion lumen 699 from the upstream side 695 to the downstream side 694 to perfuse the coronary artery 682 distal to the anastomosis site 700. If the blood flow is insufficient because of a severe stenosis or total occlusion upstream of the anastomosis site 700, blood and/or cardioplegic fluid can be injected into the catheter 691 through the luer fitting connected to the perfusion lumen 699 at the proximal end of the catheter 691.

With the anastomosis site 700 isolated from the blood flow, the graft vessel 254 can be approximated to the target vessel with the T-shaped catheter body 693 providing a guide for the approximation. The anastomosis can be performed in a blood-free environment using any one of the devices and methods described above. When the anastomosis is complete, the balloons 696, 697 can be deflated and the catheter withdrawn through the lumen 249 of the graft vessel 254.

The catheter devices described above are not limited in their use to CABG surgery. Either of the catheter devices could easily be modified to be the appropriate size for use during other bypass operations such as aorto-femoral bypass or femoral-femoral bypass.

#### Port-Access CABG Procedure

A vascular anastomosis procedure using the devices and methods of the present invention will now be described in relation to performing a proximal anastomosis on a free graft during a closed-chest or port-access coronary artery bypass graft surgical procedure. Closed-chest or port-access coronary artery bypass graft (CABG) surgery is a newly developed procedure designed to reduce the morbidity of CABG surgery as compared to the standard open-chest CABG procedure. The morbidity is reduced in the port-access CABG procedure by gaining access to the heart and the coronary arteries through one or more access ports which are made in the intercostal spaces of the patient's chest, thereby eliminating the need for a median sternotomy or other gross thoracotomy as is required in open-chest CABG surgery. A port-access coronary artery bypass graft surgical procedure using sutured

anastomosis techniques is more fully described in co-pending patent applications, serial numbers 08/023,778 and 08/281,891, which have been incorporated herein by reference.

To prepare the patient for the port-access CABG procedure, the patient is placed under general anesthesia and cardiopulmonary bypass (CPB) is established to support the patient's circulatory system during the surgical procedure. Preferably, a femoral-to-femoral CPB system is used to reduce the invasive nature of the procedure. One or more access ports 702 are made through the intercostal spaces 703 of the patient's chest by making an incision between the ribs 705 and placing a trocar with a cannula 704 through the wall of the chest. The trocar is then withdrawn, leaving the cannula 704 as an access port into the chest cavity. Typically, an endoscope, preferably a thoracoscopic surgical microscope, is placed through one of the access ports to allow direct visualization of the heart, the ascending aorta and the coronary arteries.

Meanwhile a graft vessel is prepared for creating the bypass graft which will redirect blood flow from the ascending aorta to one or more of the coronary arteries downstream of any blockage caused by atherosclerotic disease. Vessels which can be used as free grafts in CABG surgery include veins, such as the saphenous vein, arteries, such as one of the internal mammary arteries or the gastro-epiploic artery, and artificial grafts, such as Dacron or Goretex (expanded PTFE) grafts. If an autologous graft, such as a vein or an artery, is to be used, the vessel is generally harvested from the patient at this time.

Depending on the preference of the surgeon, the proximal anastomosis, which joins the graft vessel to the aorta, can be performed before or after the distal anastomosis, which joins the graft vessel to one or more of the coronary arteries. The distal anastomosis is generally performed while the patient's heart is stopped, whereas the proximal anastomosis may be performed with the heart stopped or while the heart is still beating, according to the preferences of the surgeon. To stop the heart, a special

endo-aortic clamping catheter, which is described in the  
aforementioned patent applications, is inserted into the  
ascending aorta via a percutaneous entry or a surgical cutdown  
into the femoral artery. An endo-aortic clamping balloon on  
the distal end of the catheter is inflated in the patient's  
ascending aorta to block blood flow in the patient's aorta  
downstream of the coronary arteries. Cardioplegic solution is  
immediately infused into the patient's coronary arteries  
through a lumen in the catheter to temporarily stop the  
patient's heart from beating. Alternatively, the proximal  
anastomosis can be performed while the heart is still beating  
by using a side-biting clamp or other device to isolate a  
portion of the aortic wall from the aortic blood circulation.  
With a portion of the aortic wall isolated from the systemic  
circulation by either of these methods, the proximal  
anastomosis can be performed using any of the devices and  
methods previously described herein.

The rapidity and reliability of performing the  
anastomoses using the devices and methods of the present  
invention may, in some instances, allow the entire coronary  
artery bypass procedure, including the proximal and distal  
anastomoses to be performed without the need for  
cardiopulmonary bypass support or cardioplegic arrest of the  
heart. This would be of even greater benefit to the patient  
by further decreasing the morbidity from the procedure and  
reducing the likelihood of side effects associated with CPB  
and cardioplegia. It would also be beneficial to the surgeon  
and the hospital by reducing the cost and complexity of the  
CABG procedure.

By way of example, the proximal anastomosis  
procedure will now be described using the two-part anastomosis  
staple device 100 of Fig. 1. A small incision 151 is made in  
the ascending aorta 707 at the anastomosis site 706 under  
endoscopic visualization. Then, the vessel punch mechanism  
120 and the stapling mechanism 119 with the anchor member 101  
of the anastomosis staple, which have previously been prepared  
as shown in Fig. 2, are introduced through one of the  
intercostal access ports 702 and positioned at the anastomosis

site, as in Fig. 55. The anchor member 101 is attached to the ascending aorta 707 at the anastomosis site 706 according to the procedure in Figs. 5A-5D, as follows. The anvil 136 of the vessel punch 120 is inserted through the incision 151 in the aortic wall 707, and the anchor member 101 is advanced distally so that the attachment legs 105 penetrate the aortic wall 707. Then, staple driver 127 is advanced to deform the attachment legs 105 and fasten the anchor member 101 to the exterior wall of the aorta 707. An opening 152 is then punched in the aortic wall 707 with the vessel punch 120 and the punch 120 is removed along with the tissue 153 excised by the punch. The graft insertion tool 121 and the graft vessel 148, which has previously been prepared with the coupling member 102 as shown in Fig. 6 by everting the distal end of the graft vessel 148 over the coupling member 102, are then inserted through the access port 702, as shown in Fig. 56, and the graft vessel 148 is attached to the ascending aorta 707 at the anastomosis site 706 by inserting the coupling member 102 into the anchor member 101 as shown in Figs. 5F-5G.

The bypass operation is then completed by anastomosing the distal end 708 of the graft vessel to the coronary artery 709 below the stenosis or occlusion, as shown in Fig. 57. The distal anastomosis can be performed using suturing techniques or the graft vessel 148 can be joined to the coronary artery 709 using a second anastomosis staple by following the steps shown in Figs. 5A-5C and Fig. 7C, using the embodiment of the graft insertion tool 122 illustrated in Figs. 7A-7C.

Alternatively, the proximal and distal anastomoses can be performed in the reverse order, as is preferred by some cardiac surgeons. In this case the distal anastomosis would be performed first, using the graft insertion tool 121 of Figs. 6A-6C, followed by the proximal anastomosis performed using the graft insertion tool 122 of Figs. 7A-7C. When performing the proximal anastomosis as the second anastomosis on a free graft, both ends of the graft vessel can be prepared for anastomosis by attaching a coupling member 102 to the proximal and the distal end of the graft vessel 148 and

inserting the graft vessel 148 into the chest cavity of the patient through one of the access ports 702 after attaching anchor members 101 to both the aorta 707 and the coronary artery 709. Each of the coupling members 102 can then be  
5 inserted into its respective anchor member 101 using the appropriate insertion tool 121, 122. An alternate technique is to first attach the distal end of the graft vessel 148 to a coronary artery 709 using an anastomosis staple or sutures, according to the preference of the surgeon, then, after  
10 verifying the correct length of the graft vessel, drawing the proximal end 710 of the graft vessel 148 out of the chest cavity through one of the access ports 702. The free proximal end 710 of the graft vessel 148 can be prepared under direct vision by the surgeon by passing the free end of the graft  
15 vessel through the lumen of the coupling member 102 and everting it over the distal end 115 of the coupling member 102. The coupling member 102 with the proximal end 710 of the graft vessel attached can be reinserted into the chest cavity through the access port 702 and inserted into an anchor member  
20 101 attached to the aortic wall 707 using the graft insertion tool 122 of Figs. 7A-7C. This same technique can be used with the two-piece anastomosis staple for performing a distal anastomosis on a pedicled graft vessel or for performing a distal anastomosis on a free graft after the proximal  
25 anastomosis has already been made.

The operation of the one-piece anastomosis staples of Figs. 9, 10, 11 or 12 can also be understood in relation to Figs. 55-57. The graft vessel 148 and the one-piece  
anastomosis staple 163 are prepared as described above in  
30 relation to Figs. 13 and 14. A small incision 151 is made in the ascending aorta 707 with a sharp blade at the intended anastomosis site 706, which has been isolated from the circulation with a side-biting clamp or other isolation device. An elongated punch, which may be similar to the  
35 vessel punch 120 described in relation to Figs. 2 and 5D above, is inserted through one of the access ports 702 in the patient's chest. An opening 152 is made in the wall of the ascending aorta 707 by inserting the anvil of the punch

through the incision, then pressing the actuating plunger to advance the tubular cutter over the anvil. The staple applying tool of Fig. 13 with the graft vessel 148 everted over the distal tubular extension 166 of the anastomosis staple 163, as shown in Fig. 14, is introduced through an access port 702 and positioned near the punched hole 152 in the ascending aorta 707 as illustrated in Fig. 55. The flanged end 167 of the distal tubular extension 166 is passed through the hole 152 so that it is in the position shown in Fig. 10. The wall of the ascending aorta 707 stretches slightly to allow the flange 167 to pass through the hole 152. The staple applying tool 179 is pulled back slightly to make sure the flange 167 of the staple 163 engages the interior wall of the aorta 707, then the lever 185 of the staple applying tool 179 is pulled to deform the attachment legs 168 of the staple 163 and drive them through the aortic wall 707, as shown in Fig. 10. The lever 185 is released and the staple applying tool 179 is rotated to disengage the staple retainer 188 from the tabs 170 on the proximal tubular extension 169 of the staple 163. The staple applying tool 179 is withdrawn and the anastomosis is complete.

As with the two-piece embodiment of the anastomosis staple, the one-piece anastomosis staple of Fig. 9 can also be used for creating the proximal and/or distal anastomoses on a graft vessel in either order, according to the preference of the surgeon. When performing the second anastomosis on a free graft or the distal anastomosis on a pedicled graft, the free end of the graft vessel can be drawn out of the chest cavity through one of the access ports to prepare the end of the graft vessel under direct vision by the surgeon. The graft vessel is prepared by passing the free end of the graft vessel through the lumen of the anastomosis staple and everting it over the distal flange. The anastomosis staple with the free end of the graft vessel attached can be reinserted into the chest cavity through the access port and attached to the wall of the target vessel, which may be the ascending aorta or one of the coronary arteries.

Although the foregoing description focuses on the use of the anastomosis system in closed-chest CABG surgery, the system is equally applicable to other situations that require vessel anastomosis, including, but not limited to renal artery bypass grafting, aorto-femoral bypass, femoral-femoral bypass and arterio-venous shunting, such as is commonly used for dialysis. Surgical anastomoses are also performed for various reasons on many different tubular organs of the body other than blood vessels, including the bowel, intestines, stomach and esophagus. While the devices and methods of the present invention are intended primarily for vascular anastomoses, some or all of the embodiments could also be modified for performing end-to-side anastomoses on other tubular organs. Any one of the one or two-piece embodiments of the anastomosis staple device can be supplied preattached to a prosthetic graft vessel. For instance, the two-piece anastomosis staple device could be supplied in a kit, including a natural or artificial graft that is prepared with a coupling member attached to one or both ends and one or two anchor members for attachment to the target vessel(s). Likewise, the one-piece anastomosis staple device can be supplied in a procedural kit preattached to a prosthetic graft vessel. This is equally applicable to artificial graft materials, such as PTFE or Dacron grafts, or to natural biological graft materials, including allografts of human graft vessels, or xenografts such as bovine or porcine graft vessels, either freshly harvested, glutaraldehyde treated or cryogenically preserved. An anastomotic device application instrument, such as those described above, could also be supplied in the procedural kit with one of the anastomotic devices already attached to the distal end of the instrument.

While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention, which is defined by the appended claims.

WHAT IS CLAIMED IS:

1. An anastomosis staple device for connecting a  
5 free end of a graft vessel to a wall of a target vessel such  
that a lumen in the graft vessel is in fluid communication with  
a lumen in the target vessel through an opening in the wall of  
the target vessel, the anastomosis staple device comprising:  
an anchor member, said anchor member having means for  
10 attaching said anchor member to said wall of said target vessel,  
a coupling member, said coupling member being  
configured to attach said free end of said graft vessel to said  
coupling member, and  
a coupling means for attaching said coupling member to  
15 said anchor member such that said end of said graft vessel is  
sealingly connected to said wall of said target vessel and said  
lumen of said graft vessel is in fluid communication with said  
lumen of said target vessel through said opening in said wall of  
said target vessel.  
20
2. The anastomosis staple device of claim 1 wherein  
said coupling member comprises a tubular body having an internal  
lumen of sufficient size to accommodate an external diameter of  
said graft vessel, said tubular body having a distal end  
25 configured to attach said free end of said graft vessel to said  
coupling member by everting said end of said graft vessel over  
said distal end of said tubular body.
3. The anastomosis staple device of claim 2 wherein  
30 said graft vessel comprises a conduit portion extending through  
said central lumen and an everted portion everted over said  
distal end of said coupling member, and wherein said means for  
attaching said free end of said graft vessel to said coupling  
member is atraumatic to at least said conduit portion of said  
35 graft vessel.

4. The anastomosis staple device of claim 1 wherein said means for attaching said anchor member to said wall of said target vessel is configured to attach said anchor member to an exterior surface of said wall of said target vessel at a position external to said lumen of said target vessel.

5. The anastomosis staple device of claim 1 wherein said coupling member is configured to provide an attachment which is atraumatic to said graft vessel.

6. The anastomosis staple device of claim 1 wherein said means for attaching said anchor member to said wall of said target vessel comprises a plurality of attachment legs configured to penetrate said wall of said target vessel.

7. The anastomosis staple device of claim 6 wherein each of said plurality of attachment legs is deformable from an initial configuration to a deployed configuration, the initial configuration comprising a first segment extending approximately radially from said anchor member, a transition segment connecting said first segment to a distal segment extending axially with respect to said anchor member, and a distal end configured to penetrate said wall of said target vessel.

8. The anastomosis staple device of claim 7 wherein, in said deployed configuration, each of said plurality of attachment legs penetrates said wall of said target vessel with said distal segment contacting an interior surface of said wall of said target vessel.

9. The anastomosis staple device of claim 7 wherein, in said deployed configuration, said distal segment of each of said plurality of attachment legs is approximately parallel to said first segment.

10. The anastomosis staple device of claim 7 wherein, in said deployed configuration, said plurality of attachment legs is configured to compress said wall of said target vessel radially toward said opening in said wall of said target vessel.

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11. The anastomosis staple device of claim 7 wherein, in said deployed configuration, said plurality of attachment legs is configured to axially compress said graft vessel against said wall of said target vessel.

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12. The anastomosis staple device of claim 1 wherein said anchor member comprises a ring-shaped body configured to receive said coupling member within a central opening within said ring-shaped body.

15

13. The anastomosis staple device of claim 12 wherein said coupling member has a tubular body having an internal lumen of sufficient size to accommodate an external diameter of said graft vessel, said tubular body having a distal end configured to attach said free end of said graft vessel to said coupling member by everting said end of said graft vessel over said distal end of said tubular body.

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14. The anastomosis staple device of claim 1, wherein said coupling member is initially separable from said anchor member and said coupling means is configured to allow said coupling member to be connected to said anchor member after said anchor member has been attached to said wall of said target vessel.

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15. The anastomosis staple device of claim 2, wherein said coupling member is configured to hold the everted end of said graft vessel in contact with an exterior surface of said wall of said target vessel when said coupling member is connected to said anchor member.

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16. The anastomosis staple device of claim 2, wherein said coupling member is configured to extend into said opening in said wall of said target vessel and to hold the everted end of said graft vessel within said opening in contact with an interior surface within said opening when said coupling member is connected to said anchor member.

17. The anastomosis staple device of claim 1, wherein:

10       said anchor member comprises a ring-shaped body configured to receive said coupling member within a central opening within said ring-shaped body,

15       said means for attaching said anchor member to said wall of said target vessel comprises a plurality of attachment legs extending from said ring-shaped body, said plurality of attachment legs being configured to penetrate said wall of said target vessel, and to attach said ring-shaped body to an exterior surface of said wall of said target vessel at a position external to said lumen of said target vessel,

20       said coupling member comprises a tubular body having an internal lumen of sufficient size to accommodate an external diameter of said graft vessel, said tubular body having a distal end configured to attach said free end of said graft vessel to said coupling member by everting said end of said graft vessel over said distal end of said tubular body,

25       and wherein said coupling member is initially separable from said anchor member and said coupling means is configured to allow said coupling member to be connected to said anchor member after said anchor member has been attached to said wall of said target vessel.

18. The anastomosis staple device of claim 17, wherein said coupling means comprises at least one retaining clip connected to said ring-shaped body of said anchor member, said retaining clip being configured to engage a proximal end of said tubular body of said coupling member.

19. The anastomosis staple device of claim 1,  
wherein:

said anchor member comprises a tubular extension  
configured to receive said coupling member within a central  
5 opening within said tubular extension,

said means for attaching said anchor member to said  
wall of said target vessel comprises a flange extending from a  
distal end of said tubular extension and a plurality of  
attachment legs connected to said flange, said plurality of  
10 attachment legs being configured to penetrate said wall of said  
target vessel, and to attach said flange and said tubular  
extension to an exterior surface of said wall of said target  
vessel at a position external to said lumen of said target  
vessel,

15 said coupling member comprises a tubular body having  
an internal lumen of sufficient size to accommodate an external  
diameter of said graft vessel, said tubular body having a distal  
end configured to attach said free end of said graft vessel to  
said coupling member by everting said end of said graft vessel  
20 over said distal end of said tubular body,

and wherein said coupling member is initially  
separable from said anchor member and said coupling means is  
configured to allow said coupling member to be connected to said  
anchor member after said anchor member has been attached to said  
25 wall of said target vessel.

20. The anastomosis staple device of claim 1, wherein  
said coupling means comprises an hourglass-shaped internal  
contour within said central opening of said tubular extension  
30 and a corresponding hourglass-shaped external contour on said  
tubular body of said coupling member, whereby said coupling  
member is coupled to said anchor member by insertion of the  
hourglass-shaped external contour of said tubular body into the  
hourglass-shaped internal contour within said central opening of  
35 said tubular extension.

21. The anastomosis staple device of claim 1 further comprising a graft vessel attached to said coupling member, said graft vessel being selected from the group consisting of allografts, xenografts and artificial grafts.

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22. An anastomosis staple device for connecting a free end of a graft vessel to a wall of a target vessel such that a lumen in the graft vessel is in fluid communication with a lumen in the target vessel through an opening in the wall of the target vessel, the anastomosis staple device comprising:

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a tubular member having an internal lumen of sufficient size to accommodate an external diameter of said graft vessel, said tubular member being configured to attach said free end of said graft vessel to said tubular member, and

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a plurality of attachment legs extending from said tubular member, said plurality of attachment legs being configured to at least partially penetrate said wall of said target vessel.

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23. The anastomosis staple device of claim 22 wherein said tubular member comprises a distal end configured to attach said free end of said graft vessel to said coupling member by everting said free end of said graft vessel over said distal end of said tubular member.

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24. The anastomosis staple device of claim 23, wherein said tubular member is configured to extend into said opening in said wall of said target vessel and to hold the everted end of said graft vessel within said opening in contact with an interior surface within said opening.

30

25. The anastomosis staple device of claim 22, wherein said plurality of attachment legs is configured to compress said wall of said target vessel toward said tubular member.

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26. The anastomosis staple device of claim 22 further comprising a flange connected to a distal end of said tubular member, said flange being configured to engage an interior surface of said wall of said target vessel.

5

27. The anastomosis staple device of claim 22 further comprising a flange connected to a distal end of said tubular member, said flange being configured to attach said free end of said graft vessel to said coupling member by everting said free end of said graft vessel over said flange.

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28. The anastomosis staple device of claim 27, wherein said tubular member is configured to extend into said opening in said wall of said target vessel and said flange is configured to hold the everted end of said graft vessel in contact with an interior surface of said wall of said target vessel.

15

29. The anastomosis staple device of claim 28, wherein said plurality of attachment legs is configured to compress said wall of said target vessel radially toward said tubular member.

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30. The anastomosis staple device of claim 28, wherein said plurality of attachment legs is configured to axially compress said graft vessel against said wall of said target vessel.

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31. The anastomosis staple device of claim 22, wherein each of said plurality of attachment legs has a first segment which is attached to said tubular member at an attachment point, and a second segment connected to said first segment, said second segment describing an arc having a radius of curvature with a center of rotation proximate said attachment point, said second segment having a tip configured to penetrate said wall of said target vessel,

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whereby as the first segment is rotated about said attachment point, said tip of said second segment penetrates

said wall of said target vessel and said second segment traverses said wall in an arcuate path.

32. The anastomosis staple device of claim 22,  
5 wherein each of said plurality of attachment legs has a first segment which is attached to said tubular member at an attachment point, and a second segment which describes an arc having a radius of curvature with a center of rotation proximate said attachment point, and a transition segment connecting said  
10 first segment to said second segment, said transition segment describing an arc having a radius of curvature less than the radius of curvature of said second segment, said second segment having a tip configured to penetrate said wall of said target vessel,  
15 whereby as the first segment is rotated about said attachment point, said tip of said second segment penetrates said wall of said target vessel and said second segment traverses said wall in an arcuate path, and subsequently said transition segment traverses said wall of said target vessel  
20 compressing said wall of said target vessel radially toward said tubular member.

33. The anastomosis staple device of claim 22,  
wherein each of said plurality of attachment legs has a first  
25 segment which is attached to said tubular member at an attachment point, said attachment point defining a primary center of rotation, and a second segment connected to said first segment, said second segment describing an arc having a radius of curvature with a center of rotation proximate said attachment  
30 point, said first segment having a bending point defining a secondary center of rotation on said first segment intermediate said tubular member and said second segment, said second segment having a tip configured to penetrate said wall of said target vessel,  
35 whereby as the first segment is rotated about said primary center of rotation, said tip of said second segment penetrates said wall of said target vessel and said second segment traverses said wall in an arcuate path, and subsequently

said first segment bends about said secondary center of rotation, thereby compressing said wall of said target vessel radially toward said tubular member.

5           34. The anastomosis staple device of claim 33, further comprising a ledge which extends from an exterior surface of said tubular body and which contacts each of said first segments at said bending point on said first segment intermediate said tubular member and said second segment,  
10 thereby providing said secondary center of rotation about which said first segment bends to compress said wall of said target vessel radially toward said tubular member.

          35. The anastomosis staple device of claim 22 further  
15 comprising a graft vessel attached to said tubular member, said graft vessel being selected from the group consisting of allografts, xenografts and artificial grafts.

          36. A method of performing an anastomosis to connect  
20 a free end of a graft vessel to a wall of a target vessel such that a lumen in the graft vessel is in fluid communication with a lumen in the target vessel through an opening in the wall of the target vessel, the method comprising:

          attaching an anchor member to an exterior surface of  
25 said target vessel;  
          creating an opening in said wall of said target vessel;

          attaching a coupling member to said free end of said graft vessel; and  
30           connecting said coupling member to said anchor member so as to hold said coupling member proximate said wall of said target vessel such that said end of said graft vessel is sealingly connected to said wall of said target vessel and said lumen of said graft vessel is in fluid communication with said  
35 lumen of said target vessel through said opening in said wall of said target vessel.

37. The method of claim 36 wherein said anchor member is attached to said exterior surface of said target vessel by penetrating said wall of said target vessel with a plurality of attachment legs connected to said anchor member.

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38. The method of claim 36 wherein said anchor member is attached to said exterior surface of said target vessel by penetrating said wall of said target vessel with a plurality of attachment legs connected to said anchor member, and subsequently deforming said attachment legs to affix said anchor member to said exterior surface of said target vessel.

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39. The method of claim 36 wherein said coupling member is attached to said free end of said graft vessel with an attachment that is atraumatic to said graft vessel.

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40. The method of claim 36 wherein the step of attaching said coupling member to said free end of said graft vessel includes the substeps of passing said free end of said graft vessel through an internal lumen of said coupling member and everting said end of said graft vessel over a distal surface of said coupling member.

20

41. The method of claim 40 further comprising the step of axially compressing the everted end of said graft vessel against said wall of said target vessel to create an anastomotic seal.

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42. The method of claim 36 wherein said anchor member has a ring-shaped body having an orifice therethrough and the step of connecting said coupling member to said anchor member comprises the substep of inserting said coupling member into said orifice in said anchor member.

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43. The method of claim 36 wherein said anchor member has a tubular extension connected thereto and the step of connecting said coupling member to said anchor member comprises the substep of inserting said coupling member into said tubular extension connected to said anchor member.

44. The method of claim 36 wherein the step of said anchor member is attached to said exterior surface of said target vessel prior to creating said opening in said wall of said target vessel, and wherein said opening in said wall of said target vessel is created by inserting a vessel punch through an orifice within said anchor member and cutting an opening in said wall of said target vessel in alignment with said orifice within said anchor member.

45. The method of claim 36 wherein the step of attaching an anchor member to an exterior surface of a target vessel comprises attaching said anchor member to an exterior surface of an aorta of a patient.

46. The method of claim 36 wherein the step of attaching a coupling member to a free end of a graft vessel comprises attaching said coupling member to a free end of a coronary artery bypass graft.

47. The method of claim 36 further comprising the steps of

creating at least one access port into a chest cavity of a patient through an intercostal space of the patient without cutting or substantially displacing any ribs or sternum of said patient;

inserting said anchor member into said chest cavity through said access port; and

inserting said coupling member into said chest cavity through said access port.

48. The method of claim 47 further comprising the step of:

imaging said target vessel with an endoscopic imaging instrument inserted through an access port into said chest cavity of said patient through an intercostal space of the patient.

49. The method of claim 47 wherein the step of attaching a coupling member to said free end of said graft vessel includes the substeps of passing said free end of a said graft vessel out of the chest of the patient through said at least one access port, attaching said coupling member to said free end of said graft vessel outside of the chest of the patient, and reinserting the free end of said graft vessel with the coupling member attached into the chest of the patient through said at least one access port.

50. The method of claim 40 wherein the step of connecting said coupling member to said anchor member includes the substep of approximating the everted end of said graft vessel to said exterior surface of said target vessel.

51. The method of claim 40 wherein the step of connecting said coupling member to said anchor member includes the substep of inserting said coupling member with said graft vessel attached into said opening in said wall of said target vessel thereby approximating the everted end of said graft vessel to an interior surface of said target vessel.

52. The method of claim 51 further comprising the step of radially compressing said wall of said target vessel around said coupling member to create an anastomotic seal between the everted end of said graft vessel and said wall of said target vessel.

53. A method of performing an anastomosis to connect a free end of a graft vessel to a wall of a target vessel such that a lumen in the graft vessel is in fluid communication with a lumen in the target vessel through an opening in the wall of the target vessel, the method comprising:

attaching said free end of said graft vessel to an anastomosis staple by passing the end of said graft vessel through an internal lumen in said anastomosis staple and everting said free end of said graft vessel over a distal end of said anastomosis staple;

inserting said distal end of said anastomosis staple with the everted end of said graft vessel attached through said opening in said wall of said target vessel; and

penetrating said wall of said target vessel with a plurality of attachment legs connected to said anastomosis staple to hold said anastomosis staple within said opening in said wall of said target vessel such that said end of said graft vessel is sealingly connected to said wall of said target vessel and said lumen of said graft vessel is in fluid communication with said lumen of said target vessel through said opening in said wall of said target vessel.

54. The method of claim 53 further comprising the step of compressing said wall of said target vessel radially toward said distal end of said anastomosis staple within said opening in said wall of said target vessel.

55. The method of claim 53 wherein the step of everting said free end of said graft vessel over a distal end of said anastomosis staple includes the substep of everting said free end of said graft vessel over a flange connected to said distal end of said anastomosis staple

56. The method of claim 55 further comprising the step of axially compressing the everted end of said graft vessel against said wall of said target vessel to create an anastomotic seal.

57. The method of claim 53 wherein the step of attaching said free end of said graft vessel to an anastomosis staple comprises attaching a free end of a coronary bypass graft to said anastomosis staple

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58. The method of claim 53 wherein the step of inserting said distal end of said anastomosis staple with the everted end of said graft vessel attached through said opening in said wall of said target vessel comprises inserting said  
10 distal end of said anastomosis staple with the everted end of said graft vessel attached through an opening in a wall of a coronary artery within said chest cavity of said patient.

59. The method of claim 53 wherein the step of  
15 inserting said distal end of said anastomosis staple with the everted end of said graft vessel attached through said opening in said wall of said target vessel comprises inserting said distal end of said anastomosis staple with the everted end of said graft vessel attached through an opening in a wall of an  
20 aorta within said chest cavity of said patient.

60. The method of claim 53 wherein the step of penetrating said wall of said target vessel with a plurality of attachment legs comprises applying a force in a distal direction  
25 to said plurality of attachment legs to deform said plurality of attachment legs such that a distal portion of said plurality of attachment legs penetrates said wall of said target vessel.

61. The method of claim 60 wherein the step of  
30 applying a force in a distal direction to said plurality of attachment legs to deform said plurality of attachment legs comprises causing each of said plurality of attachment legs to rotate about a pivot point such that an arc-shaped distal portion of said plurality of attachment legs penetrates said  
35 wall of said target vessel in an arcuate path.

62. The method of claim 61 further comprising a step of subsequently causing each of said plurality of attachment legs to rotate further about said pivot point such that a transition portion of said plurality of attachment legs  
5 penetrates said wall of said target vessel in an arcuate path thereby compressing said wall of said target vessel radially toward said distal end of said anastomosis staple within said opening in said wall of said target vessel.

10 63. The method of claim 61 further comprising a step of subsequently causing each of said plurality of attachment legs to rotate about a second pivot point thereby compressing said wall of said target vessel radially toward said distal end of said anastomosis staple within said opening in said wall of  
15 said target vessel.

64. The method of claim 53 further comprising the steps of

20 creating at least one access port into a chest cavity of a patient through an intercostal space of the patient without cutting or substantially displacing any ribs or sternum of said patient;

inserting said anastomosis staple into said chest cavity through said access port.

25

65. The method of claim 64 further comprising the step of:

30 imaging said target vessel with an endoscopic imaging instrument inserted through an access port into said chest cavity of said patient through an intercostal space of the patient.

66. The method of claim 64 wherein the step of attaching said free end of said graft vessel to an anastomosis  
35 staple includes the substeps of passing said free end of a said graft vessel out of the chest of the patient through said at least one access port, attaching said free end of said graft vessel to said anastomosis staple outside of the chest of the

patient, and reinserting the free end of said graft vessel with the anastomosis staple attached into the chest of the patient through said at least one access port.

5           67. A device for applying an anastomosis staple, said device comprising:

          a stapling mechanism for applying an anastomosis staple, said stapling mechanism having an internal lumen therethrough,

10           a punch means for creating an opening in a wall of a hollow organ, said punch means being removably receivable within said internal lumen of said stapling mechanism,

          whereby said device is coupled to said punch means for applying said anastomosis staple to said wall of said target

15 vessel in alignment with said opening.

          68. The device of claim 67 wherein said stapling mechanism is configured to apply said anastomosis staple to create an anastomosis between an end of a first hollow organ and  
20 a side wall of a second hollow organ wherein at least said end of said first hollow organ is everted, and said device further comprises an annular space between said punch means and said stapling mechanism sufficient to accommodate said first hollow organ within said annular space.

25           69. The device of claim 67 further comprising a graft insertion tool which is removably receivable within said central lumen of said stapling mechanism alternately with said punch means, said graft insertion tool comprising an elongated shaft  
30 having a distal end with a means for detachably holding a coupling member, said coupling member being configured for joining a graft vessel to an anchor member which is attached to an exterior surface of said wall of said target vessel.

70. An anastomosis fitting for connecting a free end of a graft vessel to a wall of a target vessel such that a lumen in the graft vessel is in fluid communication with a lumen in the target vessel through an opening in the wall of the target vessel, the anastomosis fitting comprising:

an inner flange, said inner flange having a proximal surface and a distal surface and a central orifice of sufficient size to accommodate an external diameter of said graft vessel, said inner flange providing an atraumatic attachment for said end of said graft vessel when said end of said graft vessel is passed through said central orifice and everted over said inner flange, said inner flange being insertable through said opening in said wall of said target vessel,

an outer flange, said outer flange having a proximal surface and a distal surface and a central orifice of sufficient size to accommodate the external diameter of said graft vessel, said distal surface of said outer flange being configured to contact an exterior surface of said wall of said target vessel proximate said opening, and

means for maintaining said outer flange in a selected position with respect to said inner flange such that said everted end of said graft vessel is sealingly connected to said wall of said target vessel and said lumen of said graft vessel is in fluid communication with said lumen of said target vessel through said opening in said wall of said target vessel.

71. The anastomosis fitting of claim 70, wherein said inner flange is configured such that the everted end of said graft vessel substantially covers at least said distal surface of said inner flange such that said inner flange is fluidly isolated from said lumen of said target vessel and said lumen of said graft vessel.

72. The anastomosis fitting of claim 70, further comprising a tubular body having a proximal end and a distal end, said inner flange being connected to said distal end, said tubular body having a central lumen of sufficient size to accommodate an external diameter of said graft vessel.

73. The anastomosis fitting of claim 72 wherein a proximal portion of said tubular body is configured to be slidably received in said central orifice of said outer flange, and said means for maintaining said outer flange in a selected position with respect to said inner flange comprises a locking means for locking said outer flange to said tubular body.

74. The anastomosis fitting of claim 73 wherein said locking means comprises a self-locking retaining washer slidably positioned on an exterior surface of said tubular body.

75. The anastomosis fitting of claim 71 wherein said outer flange is deformable from an initial configuration wherein said distal surface of said outer flange does not contact said exterior surface of said wall of said target vessel to a deployed configuration wherein said distal surface of said outer flange contacts said exterior surface of said wall of said target vessel.

76. The anastomosis fitting of claim 70 wherein said means for maintaining said outer flange in a selected position with respect to said inner flange comprises a deformable means for connecting said outer flange to said inner flange, whereby said deformable means can be deformed to position and hold said outer flange in a selected position with respect to said inner flange.

77. The anastomosis fitting of claim 70 wherein said outer flange is divided into a plurality of flange sectors, each of said flange sectors being connected to said inner flange by way of at least one deformable means.

78. The anastomosis fitting of claim 77 wherein said deformable means is connected to said inner flange by way of a tubular body, said tubular body having a central lumen of sufficient size to accommodate an external diameter of said graft vessel.

79. The anastomosis fitting of claim 70 wherein said outer flange comprises a tubular body connected to said inner flange, said tubular body being deformable from an undeformed configuration to an expanded configuration to form said outer  
5 flange.

80. The anastomosis fitting of claim 79 wherein said tubular body is divided into a plurality of longitudinal segments, said longitudinal segments being predisposed to expand  
10 outward when compressed axially.

81. The anastomosis fitting of claim 70, wherein said inner flange has at least two operative positions, including:  
a collapsed position wherein said inner flange has a  
15 collapsed diameter, and  
an expanded position wherein said inner flange has an expanded diameter which is greater than said collapsed diameter.

82. The anastomosis fitting of claim 81, wherein said  
20 inner flange comprises a plurality of flange sectors, said flange sectors being collapsed toward one another to occupy a diameter equal to said collapsed diameter when said inner flange is in said collapsed position, and said flange sectors being expandable away from one another to occupy a diameter equal to  
25 said expanded diameter when said inner flange is in said expanded position.

83. The anastomosis fitting of claim 82, further comprising an expansion means for expanding said inner flange  
30 from said collapsed position to said expanded position.

84. The anastomosis fitting of claim 83, wherein said expansion means comprises a tubular member which, when inserted into said central orifice between said flange sectors, forces  
35 said flange sectors from said collapsed position to said expanded position.

85. The anastomosis fitting of claim 70, wherein said inner flange comprises a plurality of initially longitudinally oriented segments, said segments being configured to expand radially in response to being compressed axially.

5

86. The anastomosis fitting of claim 85, wherein said initially longitudinally oriented segments have a proximal end which is connected to said outer flange and a distal end, said segments being configured to expand radially when said distal end is compressed axially toward said proximal end.

10

87. The anastomosis fitting of claim 86, wherein said segments have a curved portion intermediate said proximal end and said distal end predisposing said segments to expand radially when said distal end is compressed axially toward said proximal end.

15

88. The anastomosis fitting of claim 86, further comprising a means for compressing said distal end of said segments axially toward said proximal end of said segments.

20

89. The anastomosis fitting of claim 88, wherein said means for compressing comprises a tubular member having a plurality of radially extending tabs which engage said distal ends of said segments for compressing said distal end of said segments axially toward said proximal end of said segments.

25

90. The anastomosis fitting of claim 89, wherein said plurality of radially extending tabs on said tubular member are positionable to pass through a plurality of corresponding slots in said outer flange and through a plurality of spaces between said plurality of segments aligned with said slots, whereby said tubular member with said plurality of radially extending tabs is removably insertable between said plurality of segments to engage said distal ends of said segments.

30  
35

91. The anastomosis fitting of claim 70, wherein at least said central orifice of said inner flange has a geometry selected from the group consisting of circular, elliptical, oval, and teardrop-shaped.

92. The anastomosis fitting of claim 70, further comprising a secondary inner flange, said secondary inner flange having an outer diameter which is larger than an outer diameter of said inner flange and an inner diameter which is smaller than said outer diameter of said inner flange and larger than said central orifice of said inner flange.

93. The anastomosis fitting of claim 70 further comprising a secondary inner flange, said secondary inner flange having an outer diameter which is larger than an outer diameter of said inner flange and a central aperture characterized by a plurality of inwardly directed tabs which engage said inner flange at a plurality of discrete points proximate said outer diameter of said inner flange.

94. A method of performing an anastomosis to connect a free end of a graft vessel to a wall of a target vessel such that a lumen in the graft vessel is in fluid communication with a lumen in the target vessel through an opening in the wall of the target vessel, the method comprising:

attaching said free end of said graft vessel to an inner flange of an anastomotic fitting;

inserting said inner flange with said free end of said graft vessel attached through said opening in said wall of said target vessel and engaging an inner surface of said target vessel with said inner flange;

positioning an outer flange of said anastomotic fitting in contact with an exterior surface of said wall of said target vessel proximate said opening; and

coupling said inner flange and said outer flange such that said graft vessel is sealingly connected to said wall of said target vessel and said lumen of said graft vessel is in

fluid communication with said lumen of said target vessel through said opening in said wall of said target vessel.

95. The method of claim 94 wherein said free end of said graft vessel is attached to said inner flange by passing said free end of said graft vessel through an orifice within said inner flange and everting said free end of said graft vessel over said inner flange.

96. The method of claim 95 further comprising covering said inner flange with the everted end of said graft vessel to isolate said inner flange from said lumen of said target vessel and said lumen of said graft vessel.

97. The method of claim 94 further comprising compressing said wall of said target vessel between said inner flange and said outer flange.

98. The method of claim 94 further comprising compressing said wall of said target vessel and the everted end of said graft vessel between said inner flange and said outer flange.

99. The method of claim 94 wherein said inner flange of said anastomotic fitting has a compressed state and an expanded state, and wherein said free end of said graft vessel is attached to said inner flange with said inner flange in said compressed state; said inner flange with said free end of said graft vessel attached is inserted through said opening in said wall of said target vessel with said inner flange in said compressed state; and said inner flange engages said inner surface of said target vessel by expanding said inner flange to said expanded state.

100. The method of claim 94 wherein said outer flange of said anastomotic fitting is positioned in contact with said exterior surface of said wall of said target vessel by deforming said outer flange from an initial position not contacting said

exterior surface of said wall of said target vessel to a deployed position in contact with an exterior surface of said wall of said target vessel.

5           101. An anastomosis device for connecting a free end of a graft vessel to a wall of a target vessel such that a lumen in the graft vessel is in fluid communication with a lumen in the target vessel through an opening in the wall of the target vessel, the anastomosis fitting comprising:

10               a fastening flange, said fastening flange having a distal surface and a central orifice of sufficient size to accommodate an external diameter of said graft vessel, said fastening flange providing an attachment for said end of said graft vessel by passing said end of said graft vessel through  
15 said central orifice and everting said end of said graft vessel over said fastening flange,

              and a plurality of staple members movable with respect to said fastening flange, said staple members being configured to pierce the everted end of said graft vessel and to penetrate  
20 the wall of said target vessel thereby attaching said fastening flange and the everted end of said graft vessel to the wall of said target vessel.

              102. The anastomosis device of claim 101 wherein said  
25 fastening flange has a plurality of holes through said fastening flange, said holes communicating with said distal surface of said fastening flange, said staple members being slidably received within said holes.

30           103. The anastomosis device of claim 102 wherein each of said staple members has a preset curve, said preset curve being constrained in an approximately straight configuration by said holes when positioned therein, said preset curve resuming a curved configuration when said preset curve is positioned  
35 outside of said holes.

104. The anastomosis device of claim 103 wherein said preset curve of said staple members disposes a distal portion of said staple members to curve outward beyond an outer diameter of said fastening flange when said preset curve is positioned  
5 outside of said holes.

105. The anastomosis device of claim 103 wherein said staple members are made of a resilient material which biases said staple members toward the preset curved configuration.  
10

106. The anastomosis device of claim 105 wherein said resilient material is a superelastic nickel-titanium alloy.

107. The anastomosis device of claim 101 wherein each  
15 of said staple members has at least one attachment leg, said attachment leg having an approximately straight central segment, a proximal segment which makes an acute angle with respect to said central segment and a distal segment which makes an acute angle with respect to said central segment.  
20

108. The anastomosis device of claim 107 wherein said attachment leg is configured so that said proximal segment of said attachment leg bears against a proximal surface of said fastening flange and said distal segment of said attachment leg  
25 bears against an interior surface of the wall of the target vessel, thereby attaching said fastening flange to the wall of said target vessel.

109. The anastomosis device of claim 108 wherein said  
30 attachment leg is made of a resilient material having an elastic memory which biases said proximal segment against said proximal surface of said fastening flange and which biases said distal segment of said attachment leg against said interior surface of the wall of the target vessel.  
35

110. The anastomosis device of claim 107 wherein each of said plurality of staple members comprises two attachment legs, the proximal segments of said two attachment legs being attached together.

5

111. The anastomosis device of claim 110 wherein said fastening flange has a plurality of holes through said fastening flange, said holes communicating with said distal surface of said fastening flange, said holes being arranged in pairs to allow the two attachment legs of said staple members to be slidably received therein.

10

112. The anastomosis device of claim 101 wherein each of said staple members has at least one attachment leg, said attachment leg having a proximal segment and a deformable distal segment, said proximal segment being stiffer than said distal segment to resist deformation of said proximal segment.

15

113. The anastomosis device of claim 112 wherein said staple members are configured such that said distal segment is deformable to a position wherein said distal segment bears against an interior surface of said wall of said target vessel.

20

114. The anastomosis device of claim 101 wherein each of said staple members has two attachment legs, each of said attachment legs having a proximal segment and a deformable distal segment, said proximal segment being stiffer than said distal segment to resist deformation of said proximal segment, the proximal segments of said two attachment legs being attached together.

25

30

115. The anastomosis device of claim 114 wherein said proximal segment includes a stiffening means comprising a tubular member which encircles and reinforces said proximal segment.

35

116. The anastomosis device of claim 114 wherein said proximal segment has a greater cross sectional area than said distal segment.

5 117. The anastomosis device of claim 102 wherein each of said staple members has a proximal segment, a curved segment connected to said proximal segment and a distal tip connected to said curved segment, said curved segment being configured to orient said distal tip to penetrate an interior surface of the  
10 target vessel wall.

118. The anastomosis device of claim 117 wherein said distal tip of said staple member is configured to traverse the wall of the target vessel from the interior surface to an  
15 exterior surface of the target vessel and said anastomosis device further comprises means for coupling said distal tip to said fastening flange.

119. The anastomosis device of claim 118 wherein said  
20 means for attaching said distal tip to said fastening flange comprises a barb attached to said distal segment, said barb being configured to engage a ridge on said fastening flange.

120. The anastomosis device of claim 118 wherein said  
25 means for attaching said distal tip to said fastening flange comprises a locking cap couplable to said fastening flange having means to fasten said distal tip to said fastening flange.

121. The anastomosis device of claim 117 wherein said  
30 staple members are rotatable within said holes in said fastening flange to an insertion position wherein said curved segment and said distal segment are within a circle defined by an external diameter of said fastening flange to facilitate insertion of said curved segment and said distal segment through the opening  
35 in the wall of the target vessel.

122. The anastomosis device of claim 121 wherein said staple members are rotatable to a second position wherein said curved segment and said distal segment extend outward from the circle defined by the external diameter of said fastening flange.

123. The anastomosis device of claim 101, wherein when said staple members are made of a superelastic metal alloy.

124. The anastomosis device of claim 101, further comprising a plurality of outer attachment legs connected to said fastening flange, said outer attachment legs being configured to penetrate an exterior surface of said target vessel.

125. The anastomosis device of claim 124, wherein said outer attachment legs are deformable from a first position wherein said attachment legs do not contact said target vessel and a second position wherein said attachment legs penetrate said exterior surface of said target vessel.

126. The anastomosis device of claim 101, further comprising an outer flange having a distal surface configured to contact an exterior surface of said target vessel.

127. The anastomosis device of claim 126, further comprising a locking means for locking said outer flange in a selected position with respect to said fastening flange.

128. The anastomosis device of claim 127, wherein said locking means comprises a self-locking retaining washer having a central orifice slidably received on a tubular extension extending proximally from said fastening flange.

129. The anastomosis device of claim 101, wherein at least said central orifice of said fastening flange has a geometry selected from the group consisting of circular, elliptical, oval, and teardrop-shaped.

130. An improved tissue punch of the type having an anvil axially movable with respect to a tubular cutter, said anvil being configured to be slidably received within an internal lumen of said tubular cutter to punch a hole through tissue interposed between said anvil and said tubular cutter, wherein the improvement comprises:

a clamping means coupled to said tissue punch for clamping the tissue to be cut by said tissue punch.

131. The improved tissue punch of claim 130 wherein said clamping means is slidably received within said internal lumen of said tubular cutter, and wherein said clamping means has a distal surface opposing a proximal surface of said anvil wherein said tissue is clamped between said distal surface and said proximal surface.

132. The improved tissue punch of claim 130 further comprising a stapling mechanism coupled to said tissue punch, said stapling mechanism being configured to apply at least one staple to tissue surrounding said tissue punch which is clamped by said clamping means.

133. An anastomosis fitting for connecting a free end of a graft vessel to a wall of a target vessel such that a lumen in the graft vessel is in fluid communication with a lumen in the target vessel through an opening in the wall of the target vessel, the anastomosis fitting comprising:

a tubular member having an internal lumen of sufficient size to accommodate an external diameter of said graft vessel, said tubular member having a distal end with a plurality of attachment legs extending therefrom, said plurality of attachment legs being configured to penetrate at least said wall of said graft vessel from within the lumen of said target vessel,

an outer flange, said outer flange having a distal surface and a central orifice of sufficient size to accommodate the external diameter of said graft vessel, said distal surface of said outer flange being configured to contact an exterior

surface of said wall of said target vessel proximate said opening, and

means for maintaining said outer flange in a selected position with respect to said tubular member.

5

134. The anastomosis fitting of claim 133 wherein each of said plurality of attachment legs have a first segment extending radially from said distal end of said tubular member and a second segment extending proximally from said first

10 segment.

135. The anastomosis fitting of claim 133 wherein said central orifice of said outer flange is slidably received over an exterior surface of said tubular member, and wherein said means for maintaining said outer flange in a selected position with respect to said tubular member comprises a self-locking retaining washer slidably positioned on an exterior surface of said tubular member.

15

20

136. A method of performing an anastomosis to connect a free end of a graft vessel to a wall of a target vessel such that a lumen in the graft vessel is in fluid communication with a lumen in the target vessel through an opening in the wall of the target vessel, the method comprising:

25

passing said graft vessel through an internal lumen of a tubular member;

everting said free end of said graft vessel;

penetrating the everted end of said graft vessel with a plurality of attachment legs extending from a distal end of said tubular member;

30

inserting said plurality of attachment legs through said opening in said wall of said target vessel;

penetrating an interior surface of said wall of said target vessel with said plurality of attachment legs;

35

positioning a distal surface of an outer flange in contact with an exterior surface of said wall of said target vessel proximate said opening; and

locking said outer flange in a selected position with respect to said tubular member.

137. An anastomosis device comprising:

5 an anastomosis means for connecting a free end of a graft vessel to a wall of a target vessel such that a lumen in the graft vessel is in fluid communication with a lumen in the target vessel through an opening in the wall of the target vessel, and

10 a flexible tubular extension extending from said anastomosis means, said flexible tubular extension encircling and supporting at least a portion of said graft vessel.

138. The anastomosis device of claim 137 wherein said  
15 flexible tubular extension has a distal end proximate said anastomosis means and a proximal end more distant from said anastomosis means, said flexible tubular extension being progressively more flexible from said distal end to said proximal end, said flexible tubular extension being  
20 progressively more radially compliant from said distal end to said proximal end, and said flexible tubular extension having a diameter which becomes progressively larger from said distal end to said proximal end.

25 139. An anastomosis device for connecting a free end of a graft vessel to a wall of a target vessel such that a lumen in the graft vessel is in fluid communication with a lumen in the target vessel through an opening in the wall of the target vessel, the anastomosis fitting comprising:

30 a first ring having a distal end with a plurality of staple members depending therefrom, and

a second ring concentrically positionable with respect to said first ring, said second ring having a distal end with a plurality of staple members depending therefrom.

140. The anastomosis device of claim 139 wherein the staple members depending from said first ring are angled in a clockwise direction and wherein the staple members depending from said second ring are angled in a counterclockwise direction.

141. The anastomosis device of claim 139 wherein said first ring is rotatable with respect to said second ring, and wherein said anastomosis device further comprises a locking means for locking said first ring in a desired rotational orientation with respect to said second ring.

142. A catheter apparatus for nonocclusively isolating a section of a tubular organ from fluid flow within said tubular organ, said catheter apparatus comprising:

a distal balloon and means for inflating said distal balloon,

a proximal balloon and means for inflating said proximal balloon,

a perfusion tube to which said proximal and distal balloons are attached in spaced apart positions, said perfusion tube having a proximal opening proximal to said proximal balloon, a distal opening distal to said distal balloon and a perfusion lumen therebetween, and

an elongated catheter shaft connected to said perfusion tube between said proximal balloon and said distal balloon in a T configuration.

143. An improved method for performing a vascular anastomosis of the type in which an end of a graft vessel is anastomosed to a wall of a target vessel at a selected anastomosis site, wherein the improvement comprises performing the steps of:

isolating said anastomosis site within said target vessel from blood flow by inserting a catheter into a lumen of said target vessel, inflating a first balloon on said catheter upstream of said anastomosis site and inflating a second balloon on said catheter downstream of said anastomosis site;

perfusing said target vessel downstream of said second balloon with blood delivered through a perfusion lumen of said catheter; and

performing the anastomosis at said anastomosis site  
5 between said first balloon and said second balloon.

144. The improved method for performing a vascular anastomosis of claim 143, wherein said target vessel downstream of said second balloon is perfused with blood which enters said  
10 perfusion lumen of said catheter at a point in said target vessel upstream of said first balloon.

145. The improved method for performing a vascular anastomosis of claim 143, wherein said target vessel is an aorta  
15 connected to a heart of a patient and said anastomosis is performed while the heart of the patient is beating.

146. An anastomosis system comprising:

an anastomosis staple means for connecting a free end  
20 of a graft vessel to a wall of a target vessel such that a lumen in the graft vessel is in fluid communication with a lumen in the target vessel through an opening in the wall of the target vessel, and

a staple applying means for applying said anastomosis  
25 staple means such that said end of said graft vessel is sealingly connected to said wall of said target vessel and said lumen of said graft vessel is in fluid communication with said lumen of said target vessel through said opening in said wall of said target vessel.

30

147. The anastomosis system of claim 146 wherein said staple applying means comprises a staple holding means for holding said anastomosis staple and a concentric staple driver having an annular staple deforming surface which is axially  
35 displaceable with respect to said staple holding means.

148. The anastomosis system of claim 146 wherein said staple applying means comprises a staple holding means for holding said anastomosis staple and a concentric staple driver having an annular staple deforming surface which is axially  
5 displaceable with respect to said staple holding means.

149. The anastomosis system of claim 146 wherein said anastomosis staple means comprises an atraumatic means for attaching said free end of said graft vessel to said anastomosis  
10 staple means and a plurality of attachment legs peripherally arranged about said atraumatic means, said plurality of attachment legs being configured for penetration of said wall of said target vessel.

150. The anastomosis system of claim 149 wherein said atraumatic means comprises a tubular body having an internal lumen of sufficient size to accommodate an external diameter of said graft vessel and a distal end configured to receive said  
15 graft vessel by eversion of said free end of said graft vessel over said distal end of said tubular body.  
20

151. The anastomosis system of claim 150 wherein said atraumatic means further comprises a flange connected to said distal end of said tubular body, said flange being configured to  
25 receive said graft vessel by eversion of said free end of said graft vessel over said flange.

152. The anastomosis system of claim 149 wherein said atraumatic means comprises a coupling member configured for  
30 joining said graft vessel to an anchor member which is attached to an exterior surface of said wall of said target vessel.

153. The anastomosis system of claim 152 further comprising a graft insertion means for joining said coupling  
35 member to said anchor member.

155

154. The anastomosis system of claim 146 further comprising a punch means for creating an opening in a wall of said target vessel, said punch means being removably receivable within an internal lumen of said staple applying means.

5

155. The anastomosis system of claim 146 further comprising an intraluminal means for isolating an anastomosis site on a wall of said target vessel from blood flow within said target vessel.

10

156. The anastomosis system of claim 146 further comprising an intraluminal means for isolating an anastomosis site on a wall of said target vessel from blood flow within said target vessel and for perfusing said target vessel with blood downstream of said anastomosis site.

15

157. The anastomosis system of claim 146 further comprising a graft vessel attached to said anastomosis staple, said graft vessel being selected from the group consisting of allografts, xenografts and artificial grafts.

20

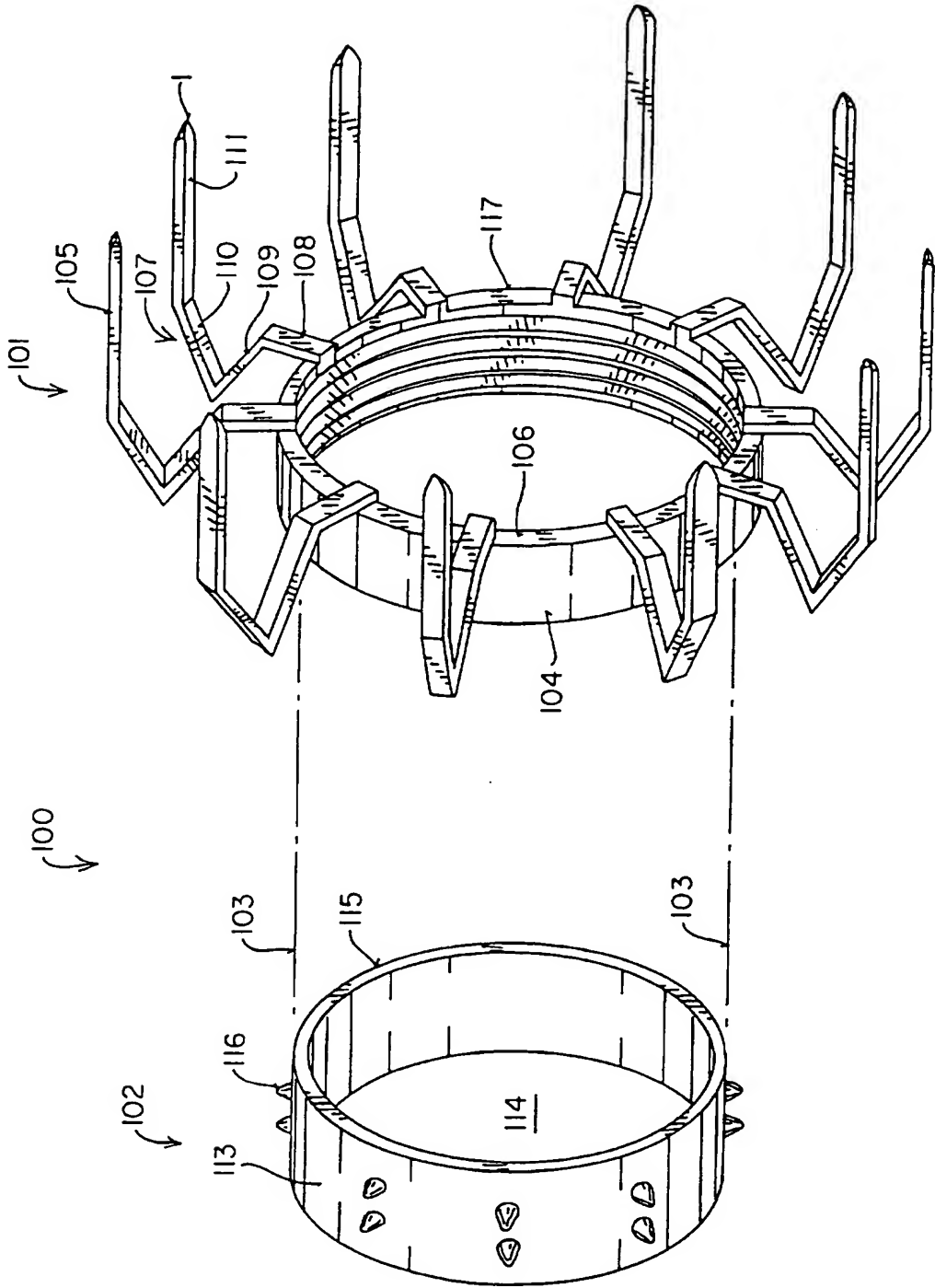


FIG. 1

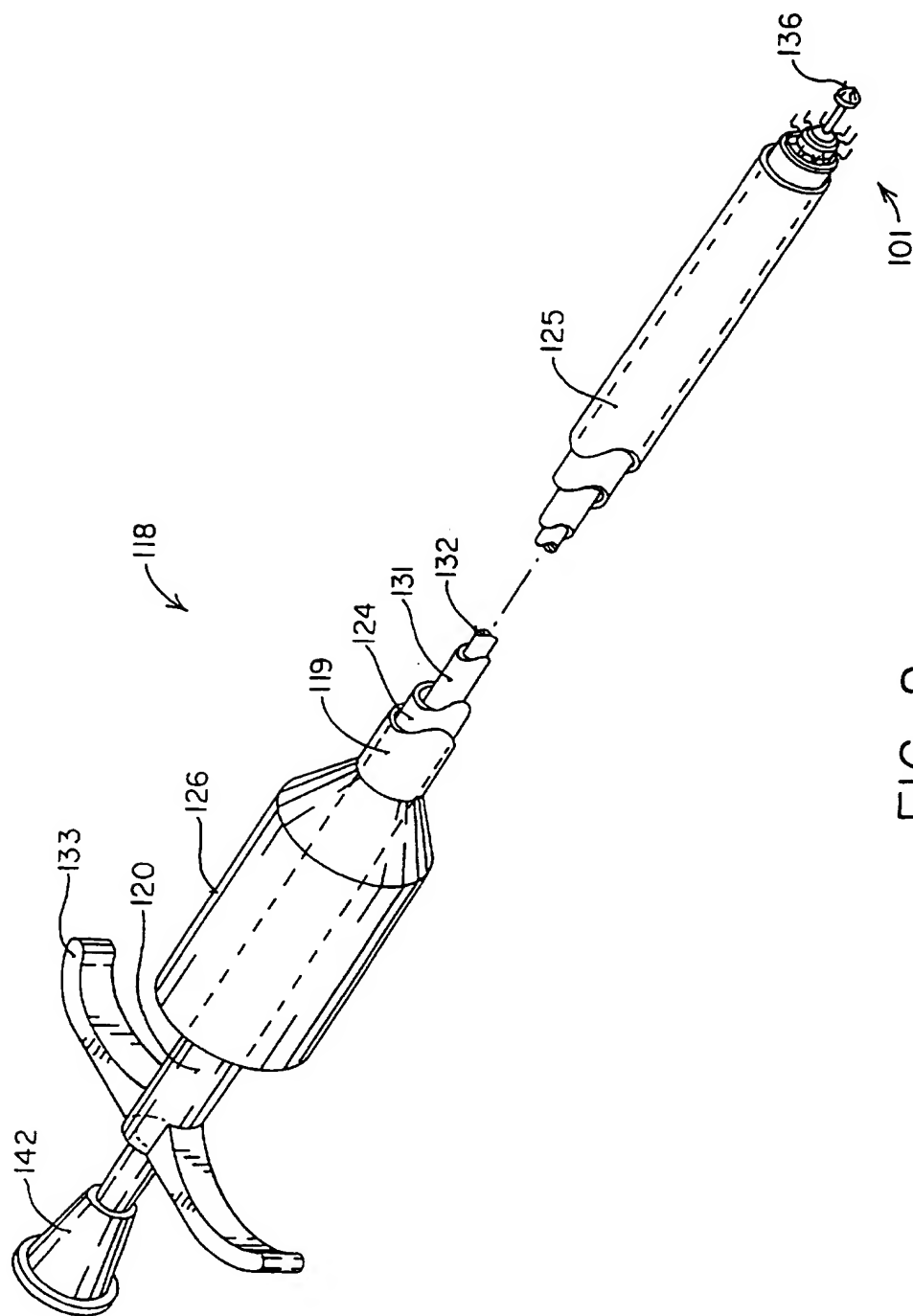


FIG. 2

SUBSTITUTE SHEET (RULE 26)

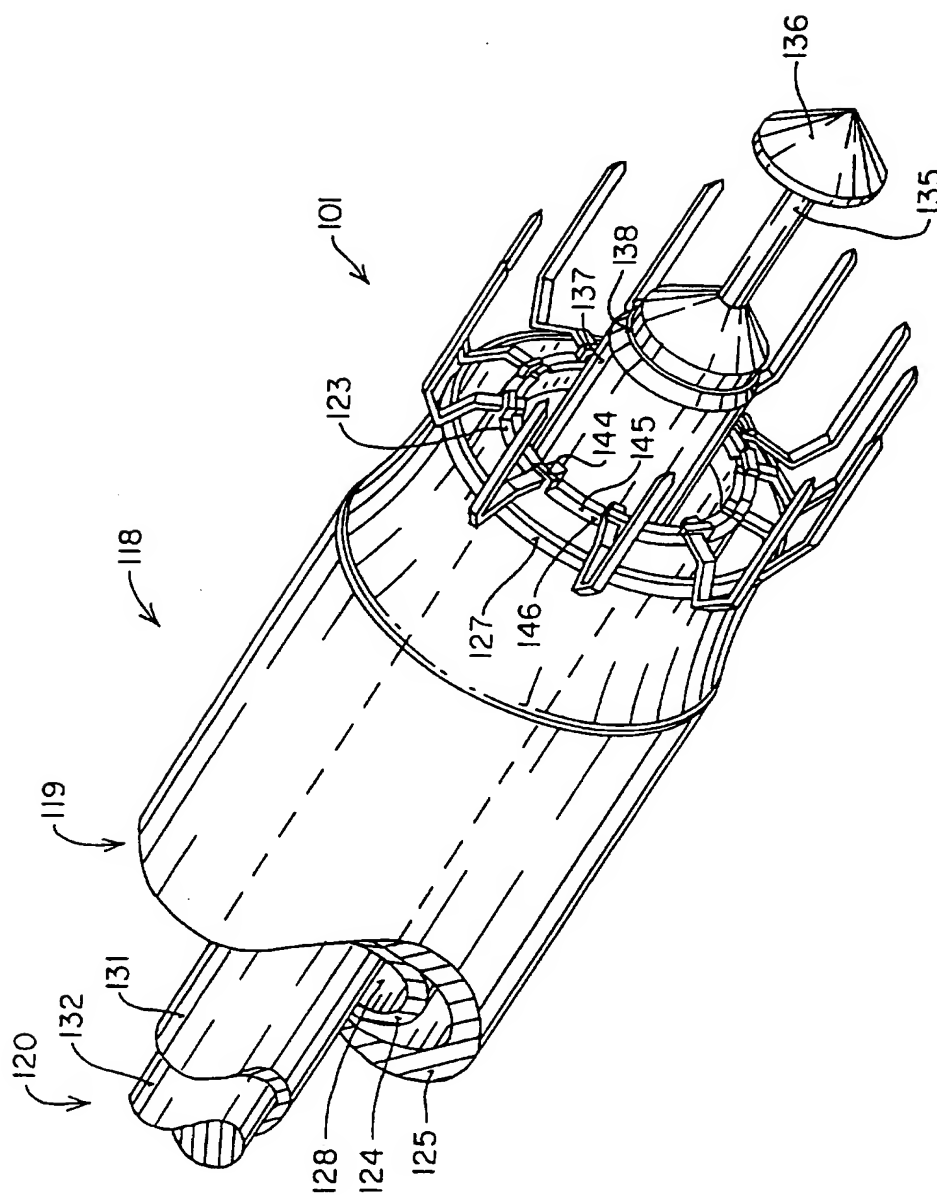


FIG. 3

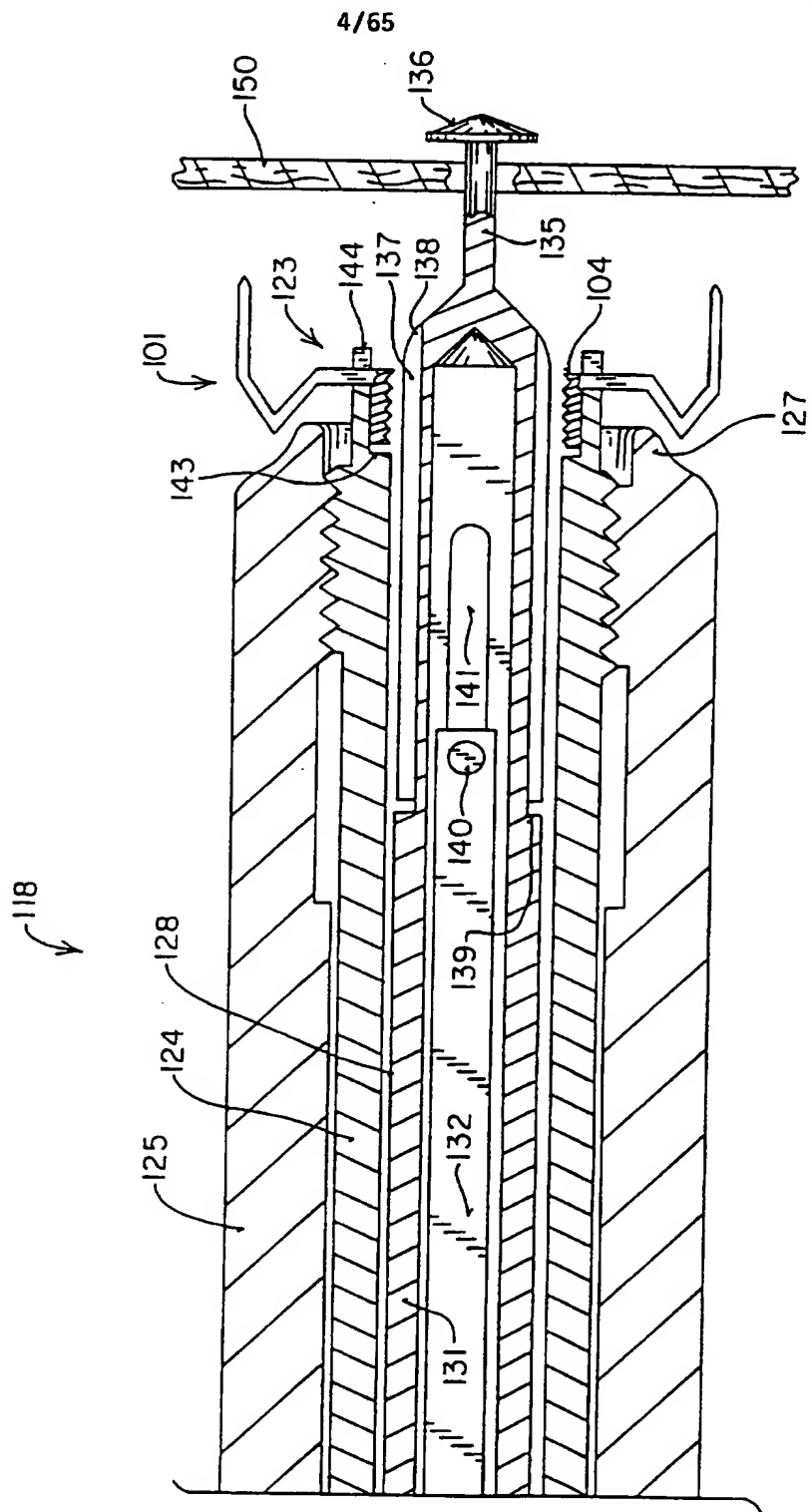


FIG. 4

SUBSTITUTE SHEET (RULE 26)

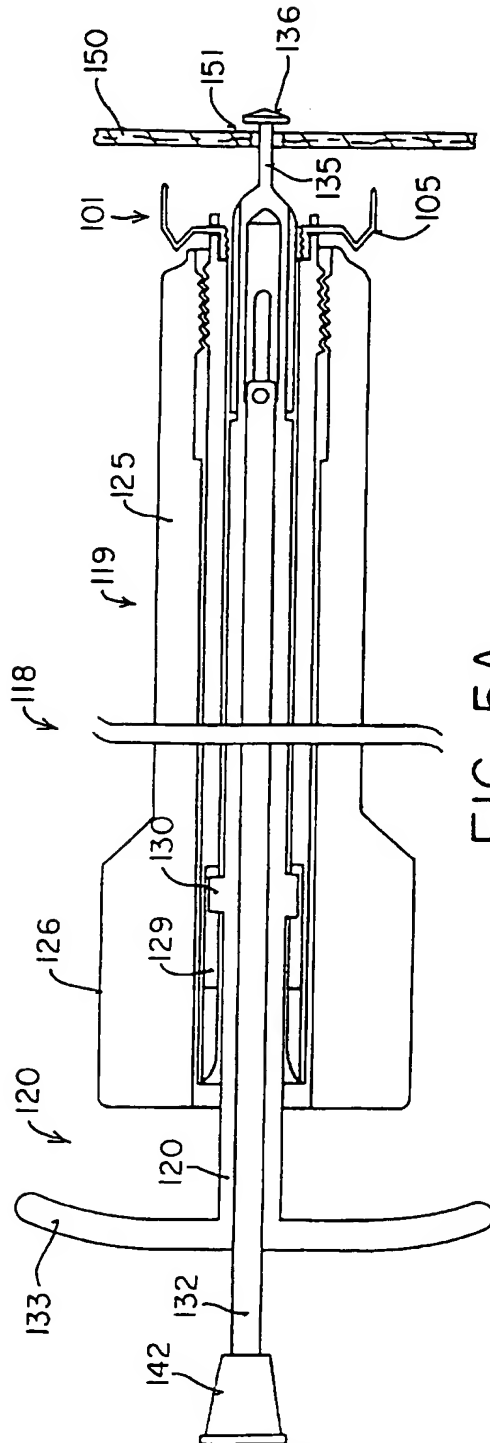


FIG. 5A

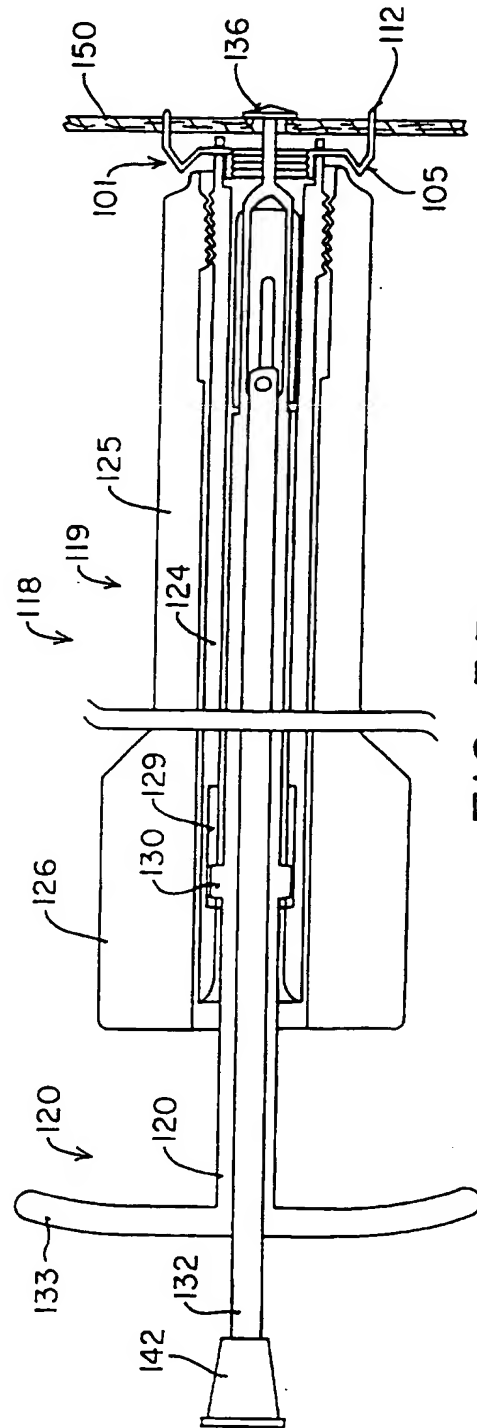


FIG. 5B

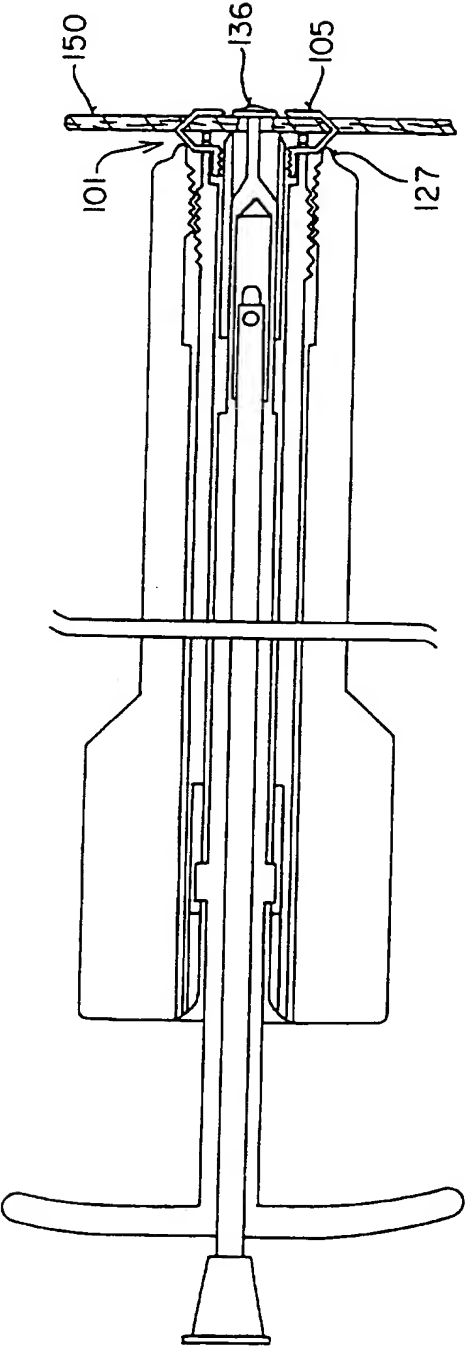


FIG. 5C

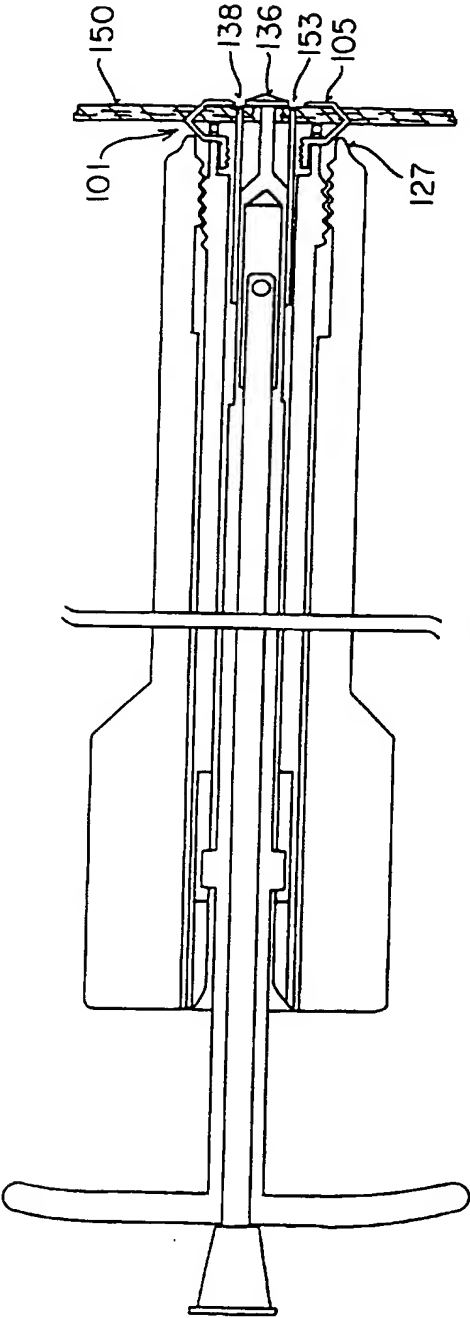


FIG. 5D

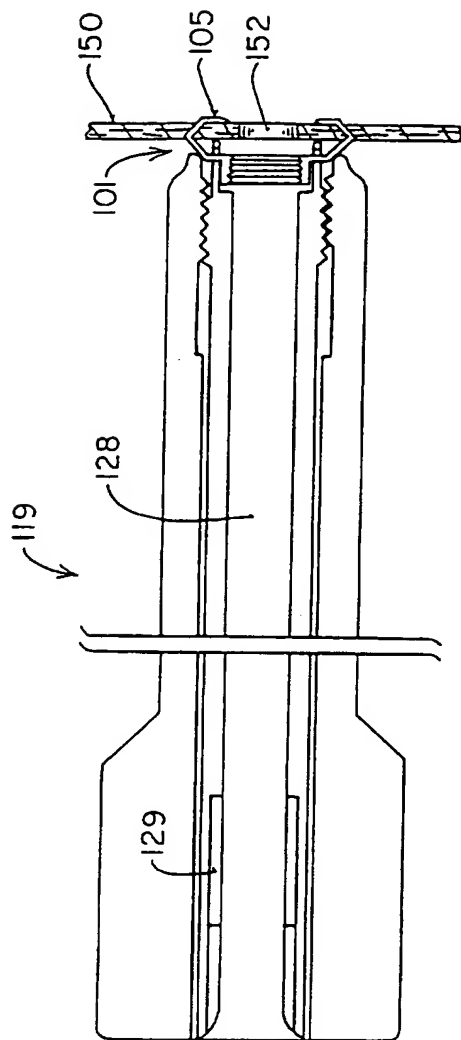


FIG. 5E

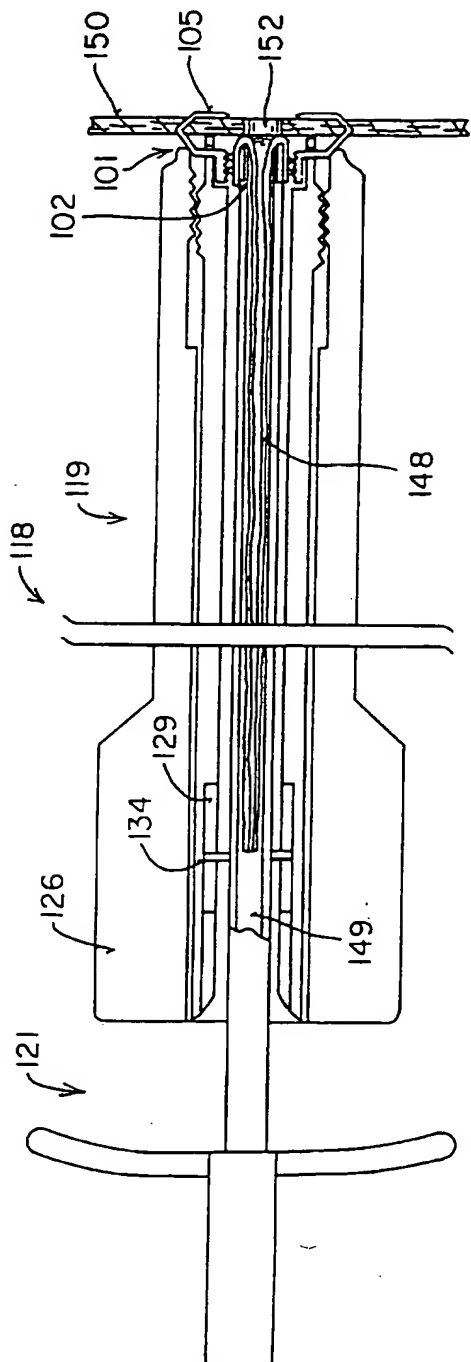


FIG. 5F

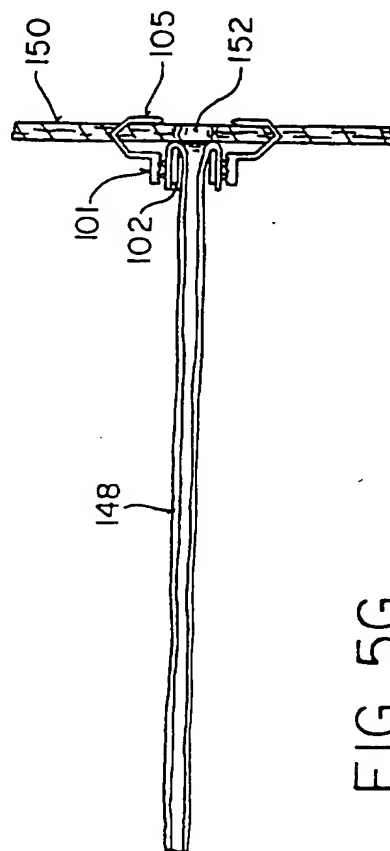


FIG. 5G

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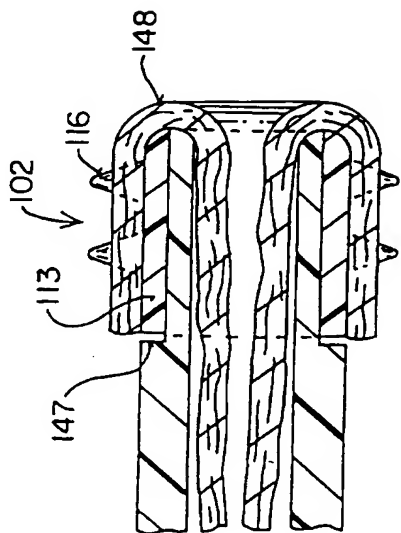


FIG. 6B

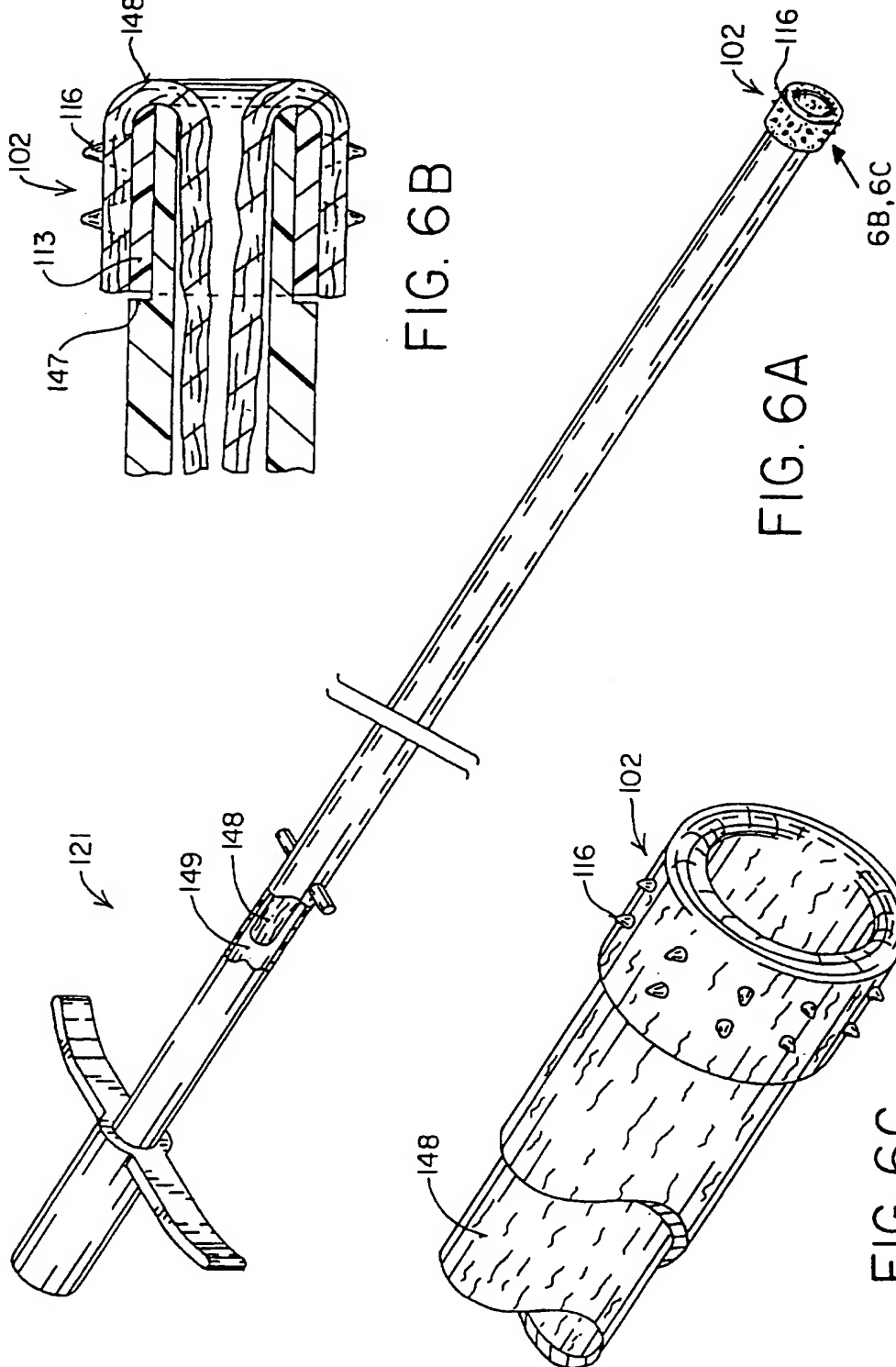


FIG. 6A

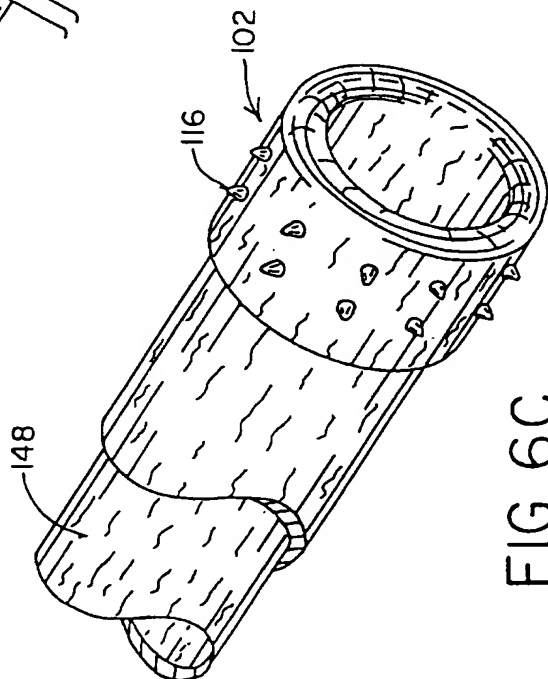


FIG. 6C

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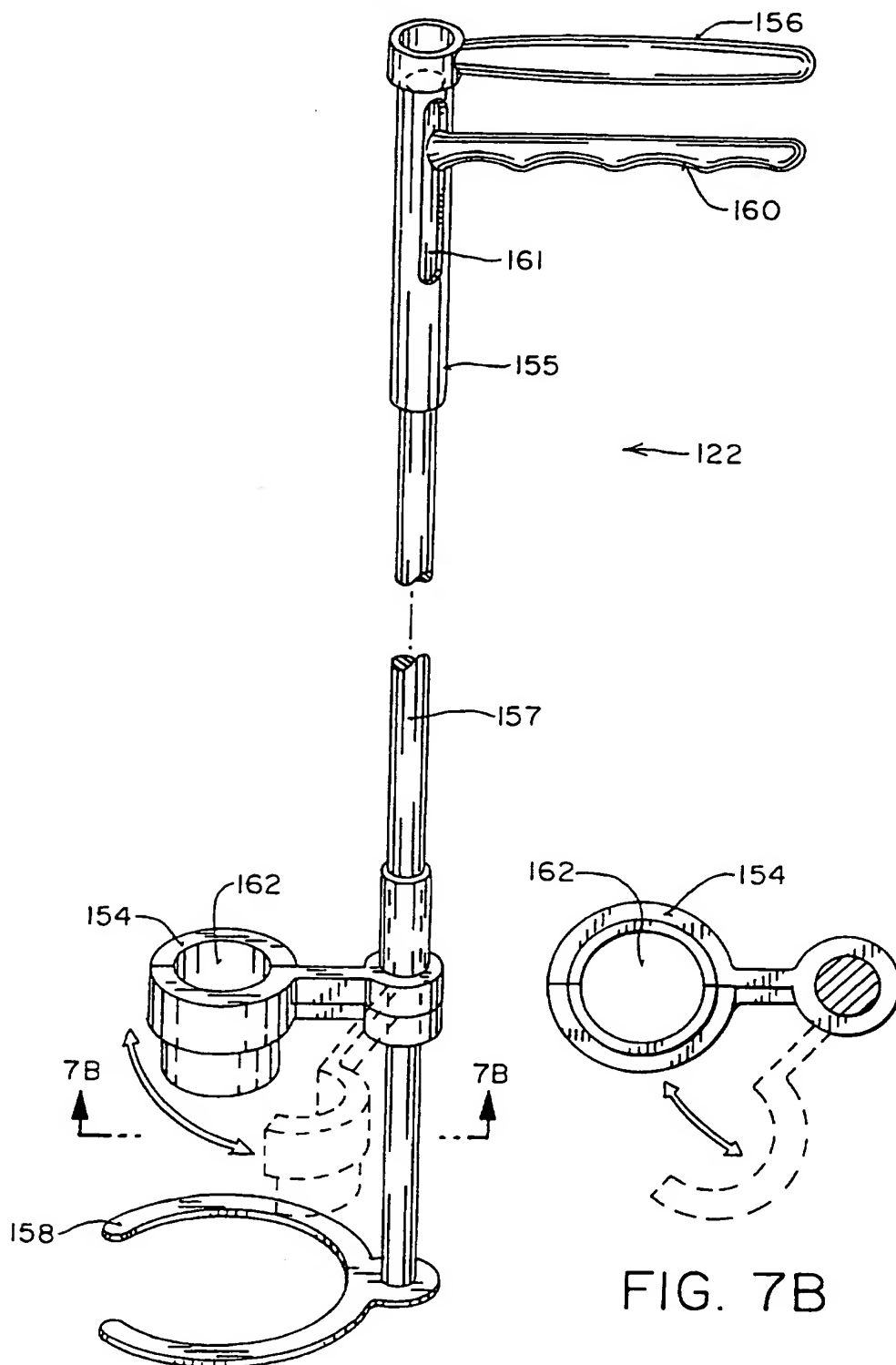


FIG. 7A

FIG. 7B

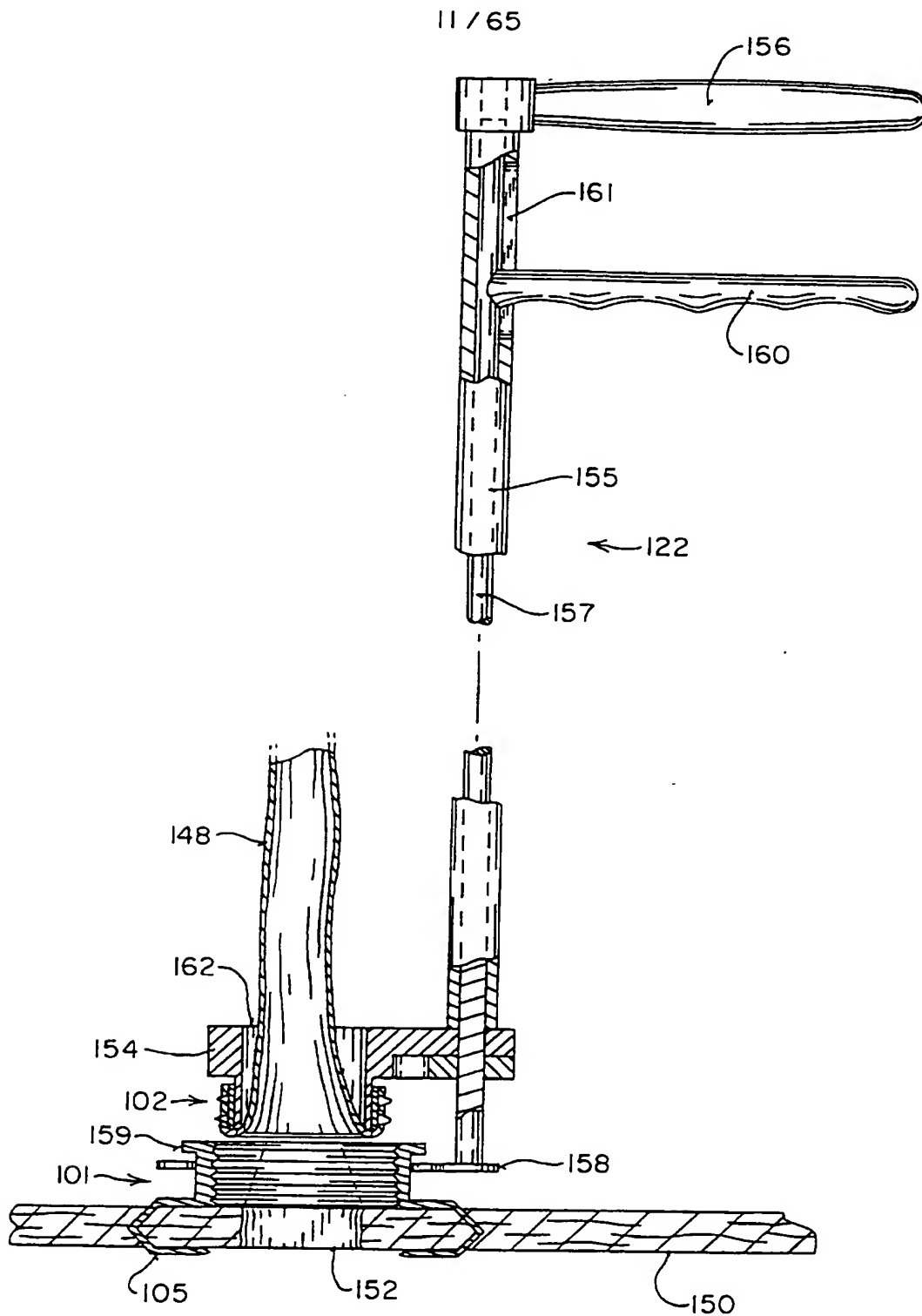
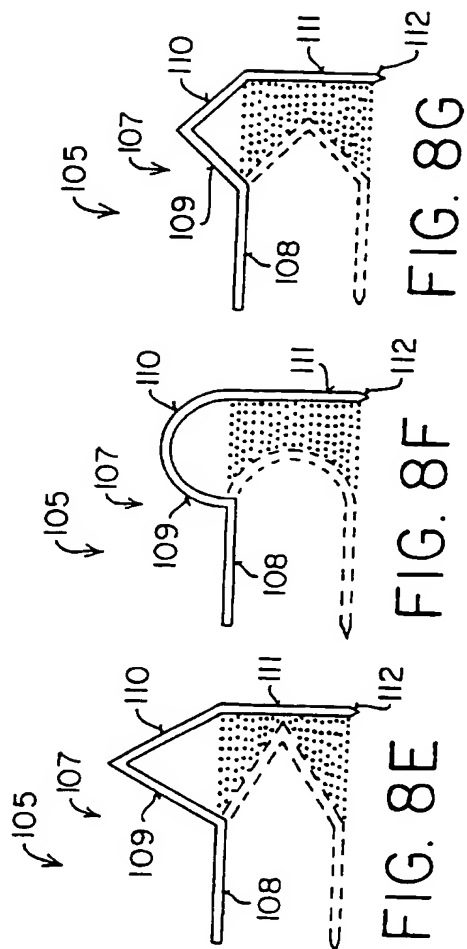
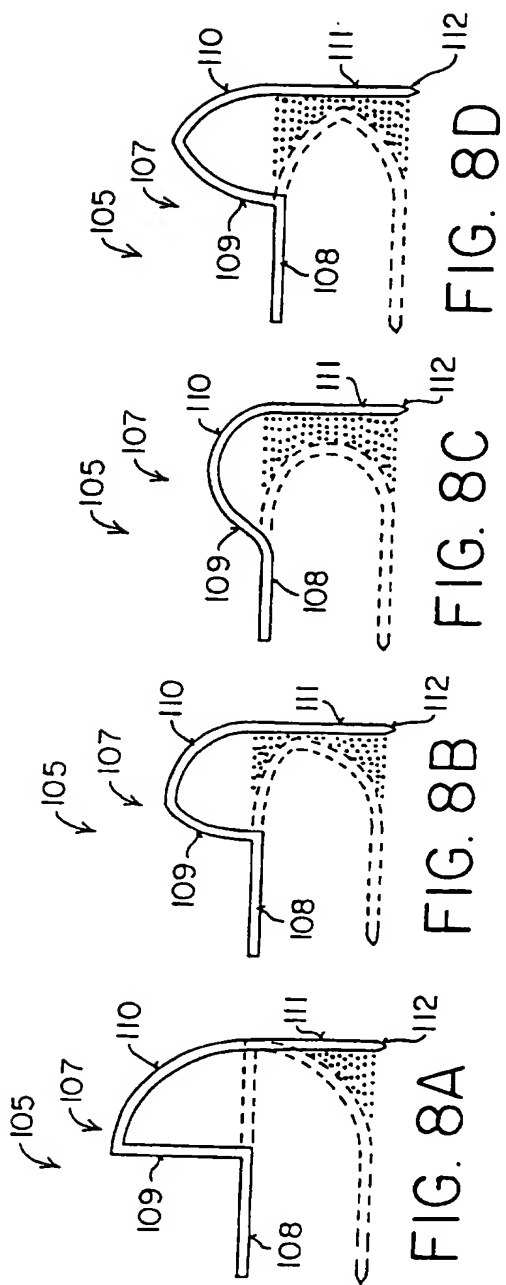


FIG. 7C  
SUBSTITUTE SHEET (RULE 26)



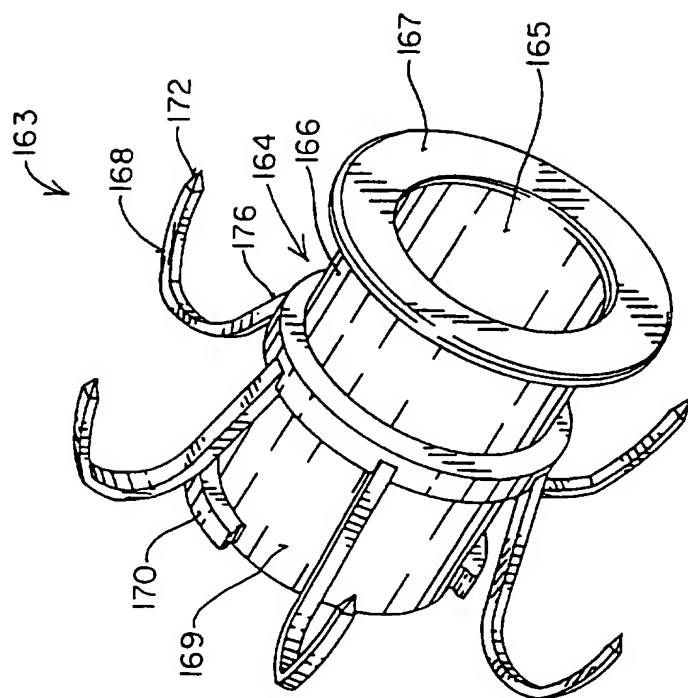


FIG. 9

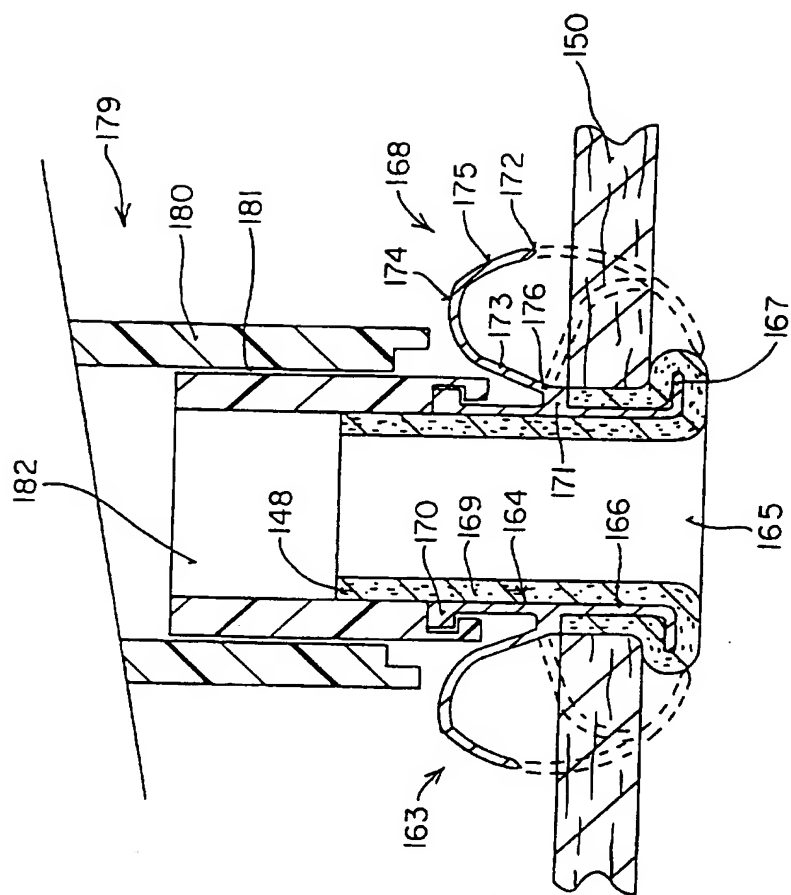


FIG. 10

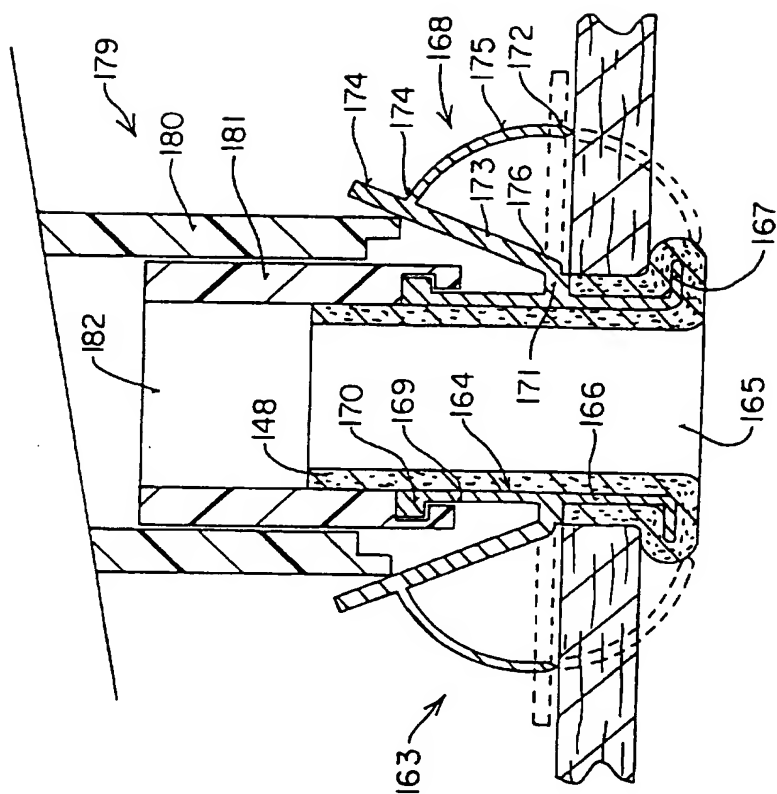


FIG. 11

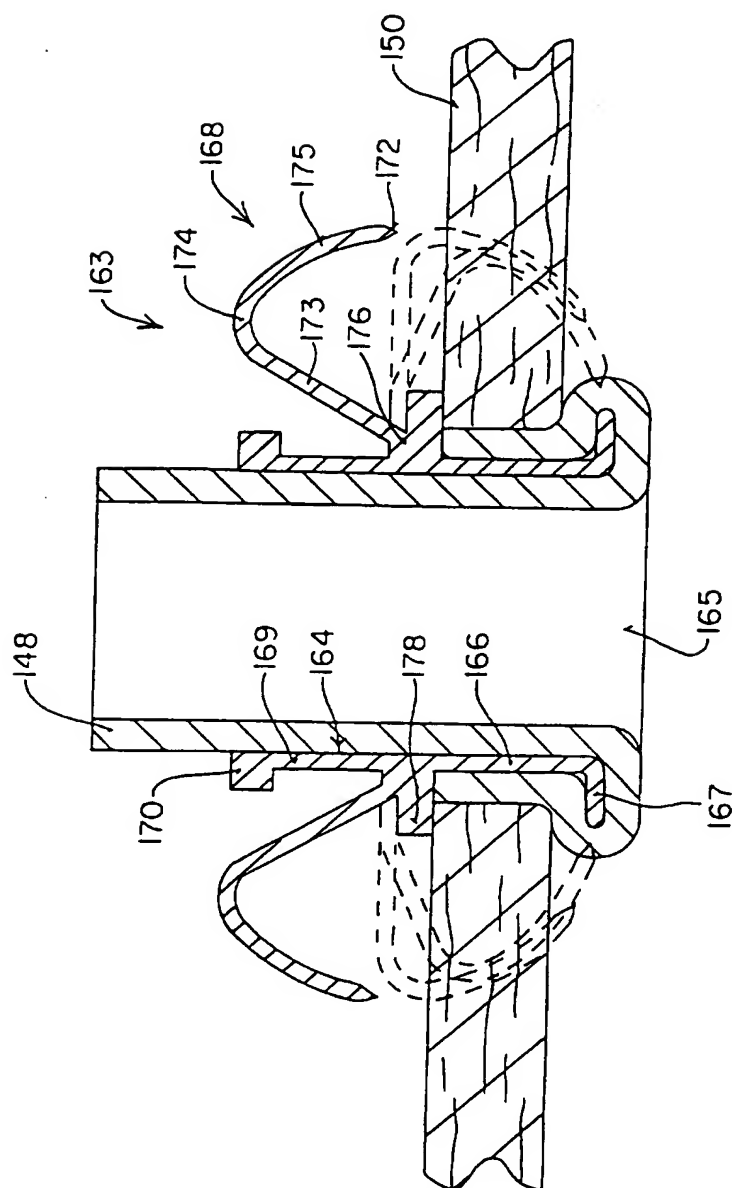


FIG. 12

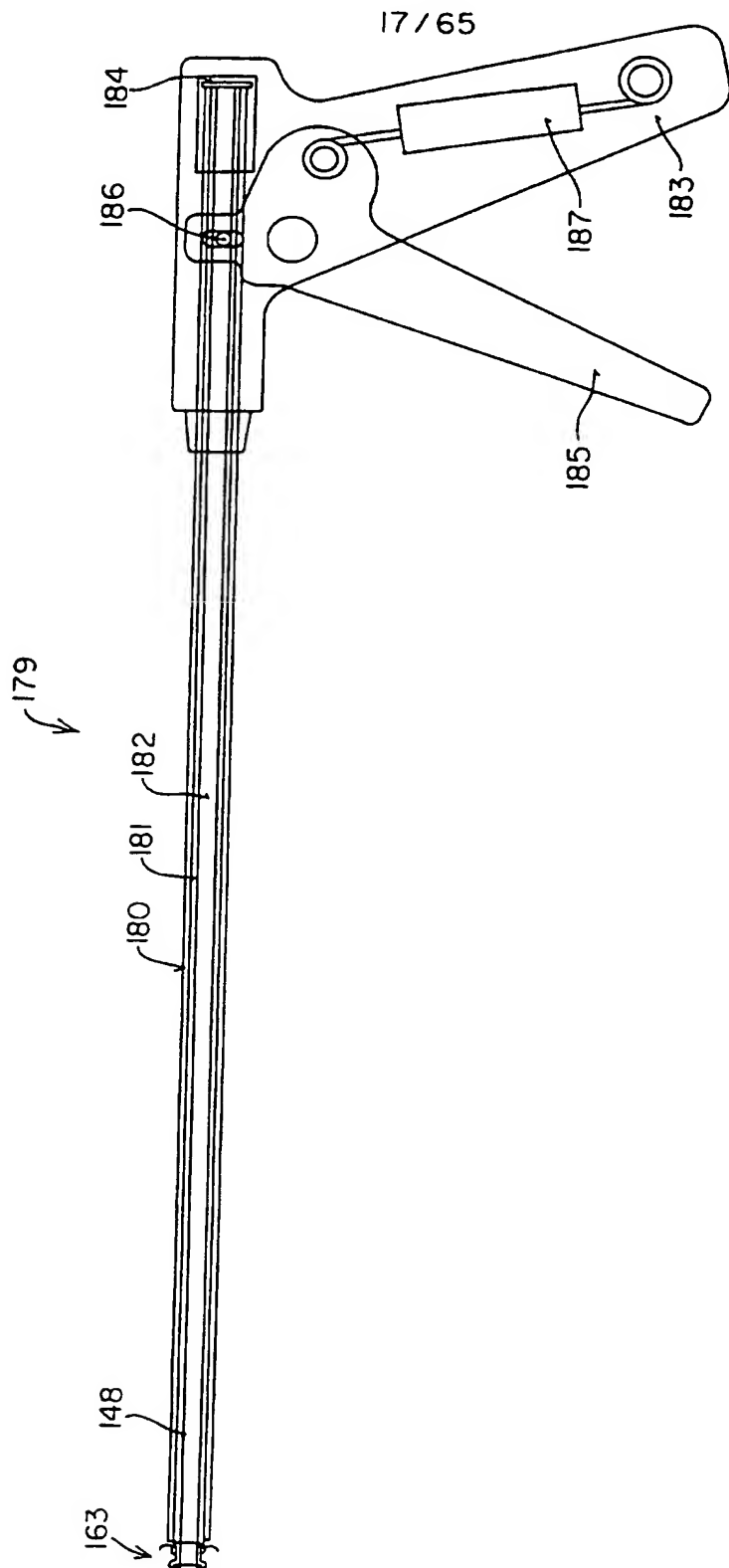


FIG. 13

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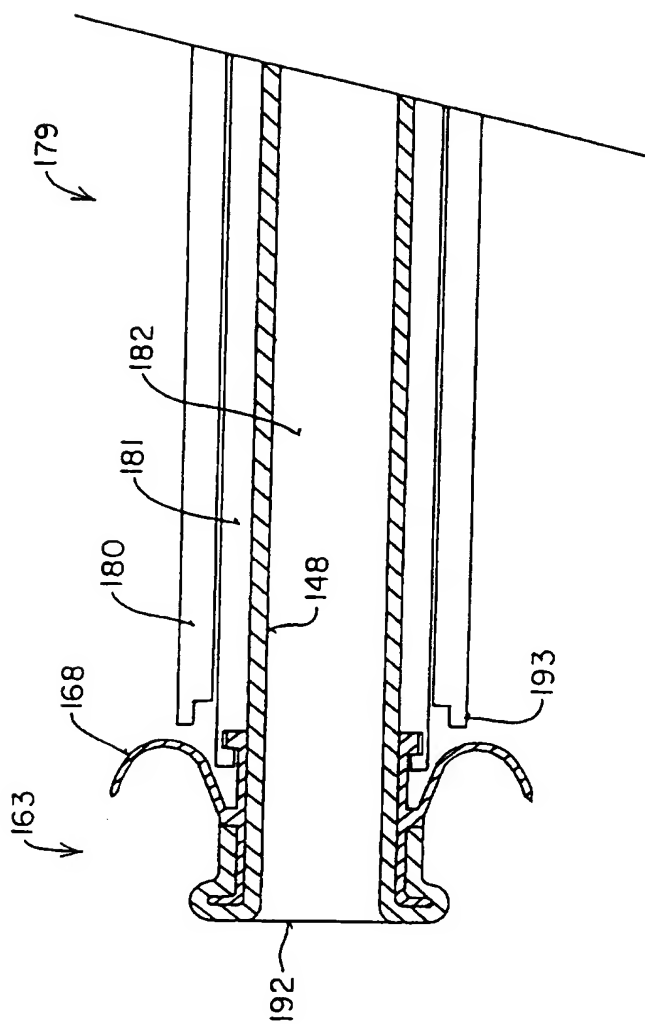
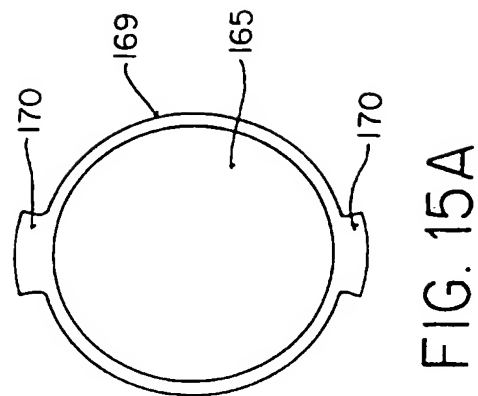
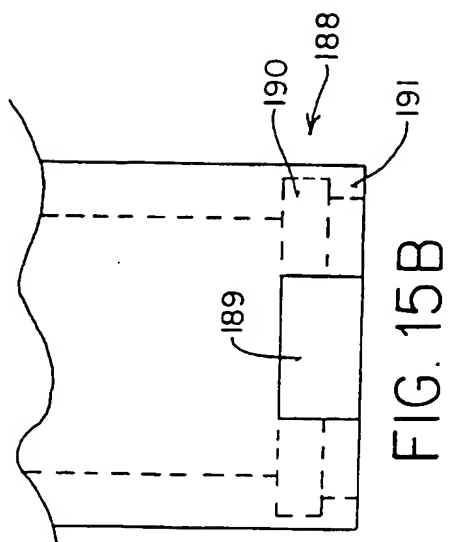


FIG. 14



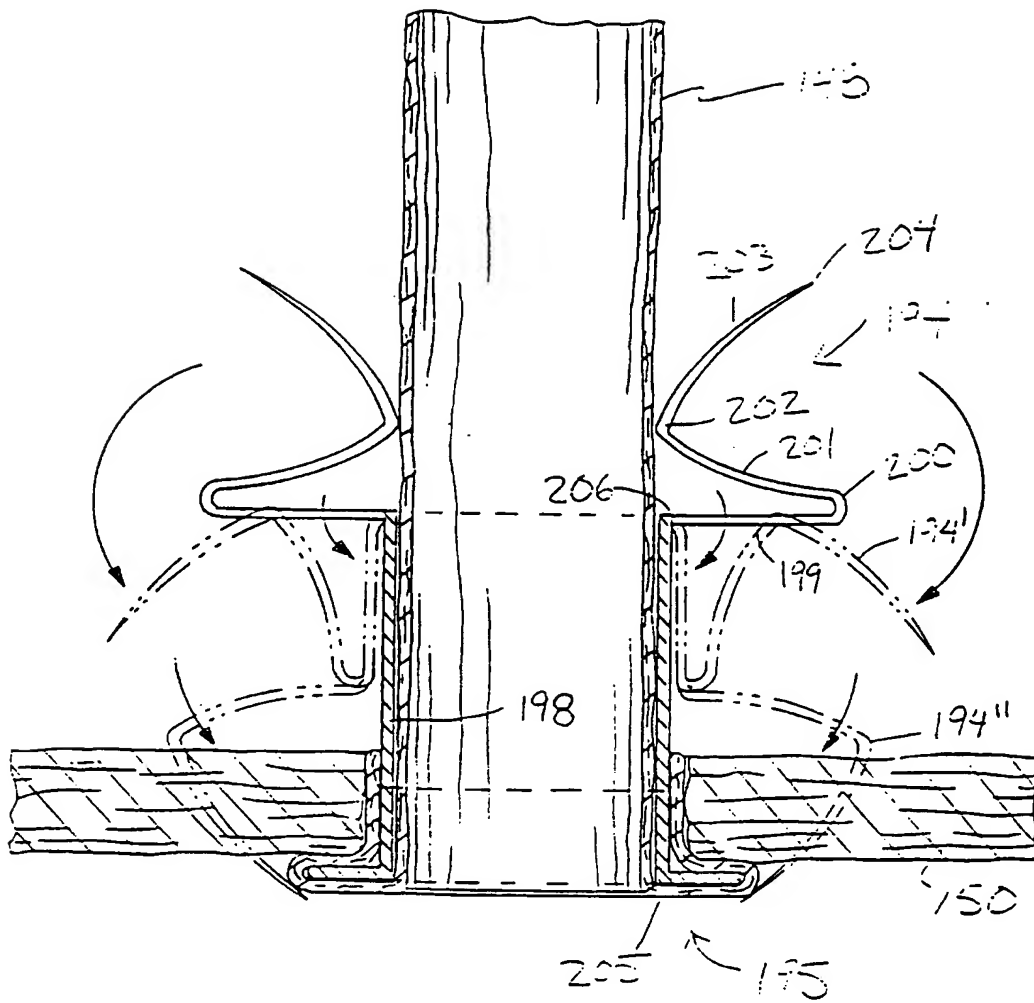


FIG. 16

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FIG. 17B

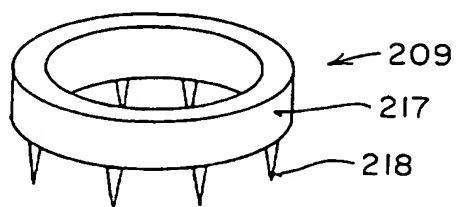


FIG. 17A

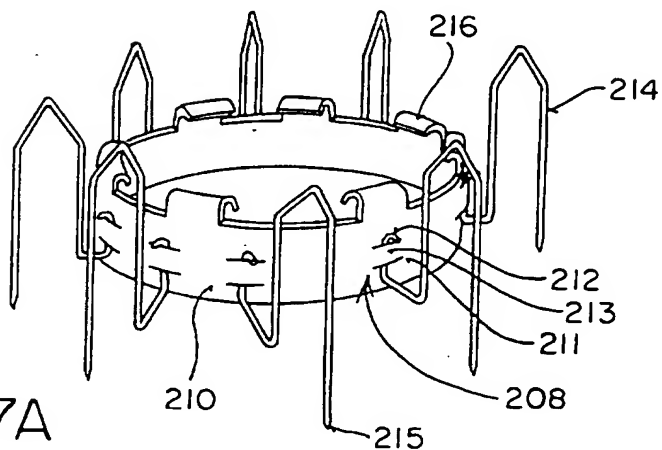


FIG. 17C

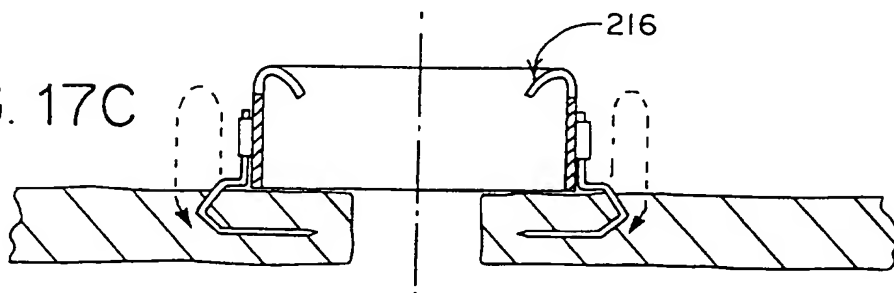
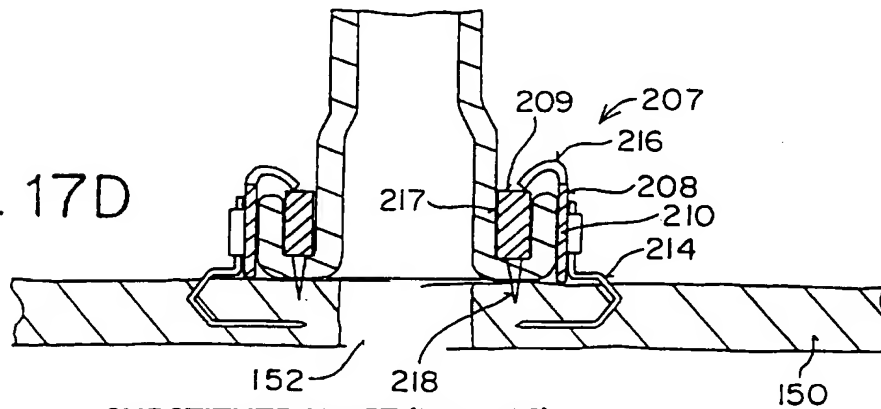


FIG. 17D



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FIG. 18A

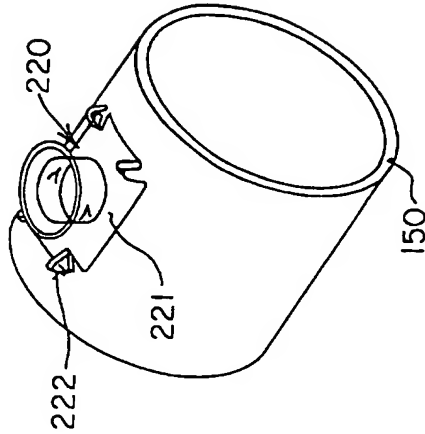


FIG. 18B

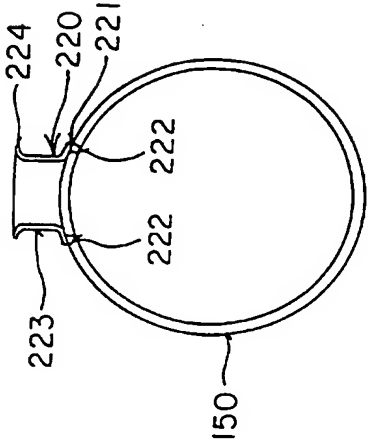


FIG. 18C

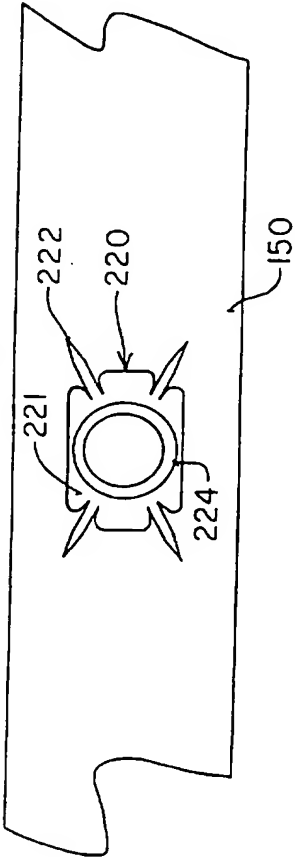


FIG. 18D



FIG. 18E

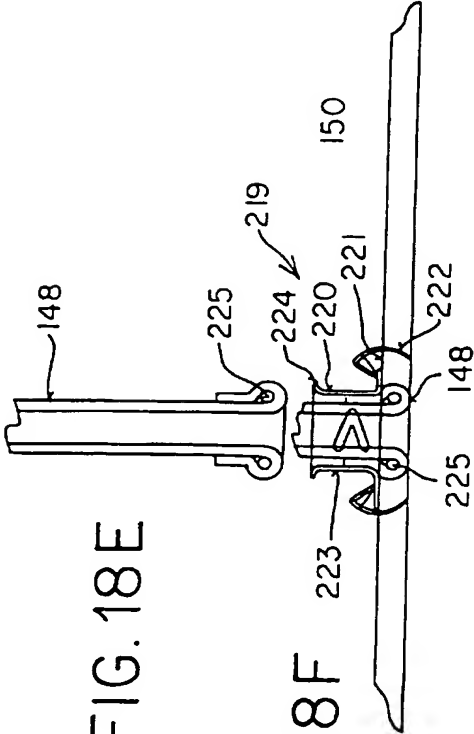
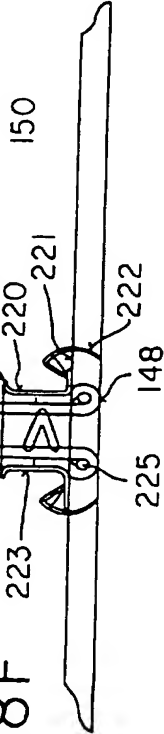


FIG. 18F



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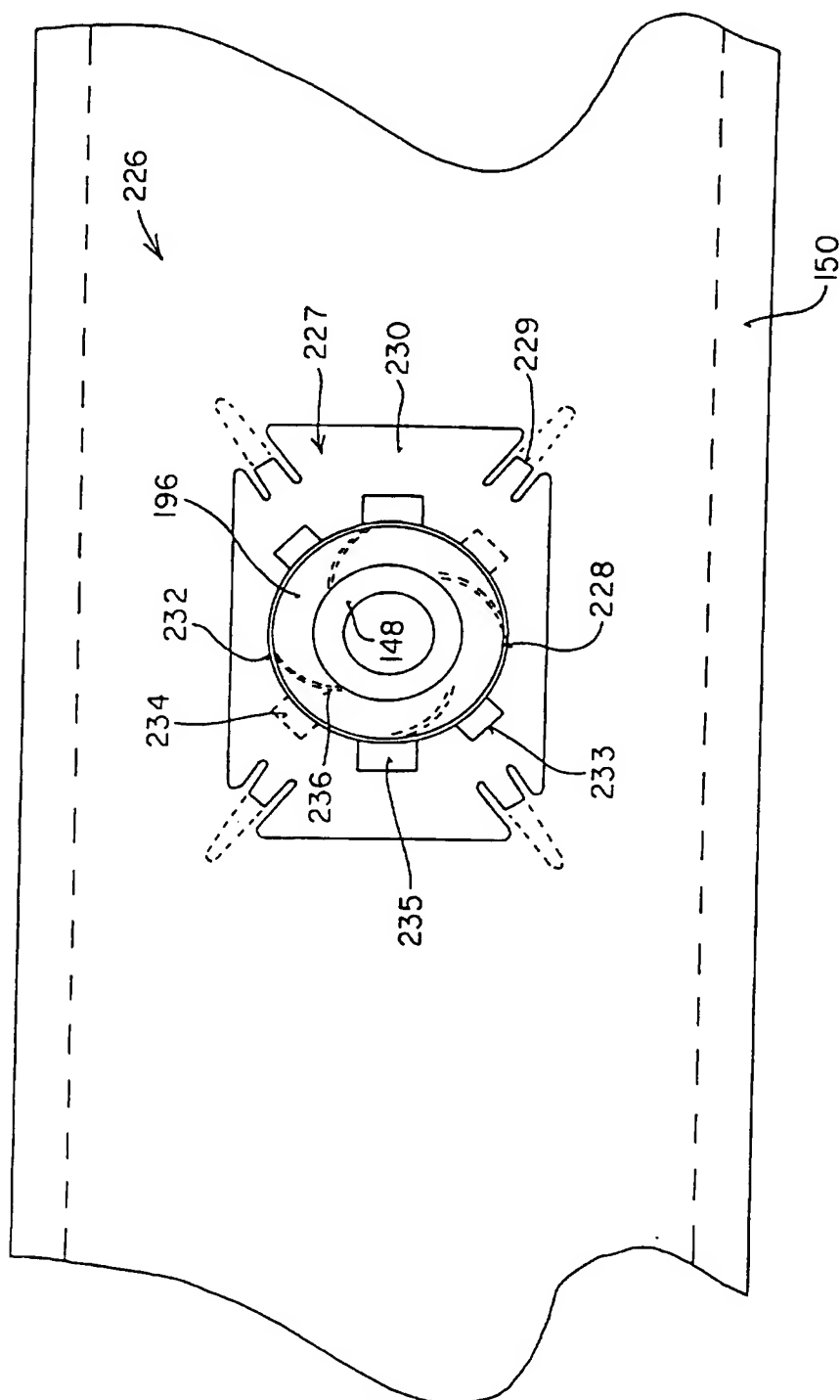


FIG. 19A

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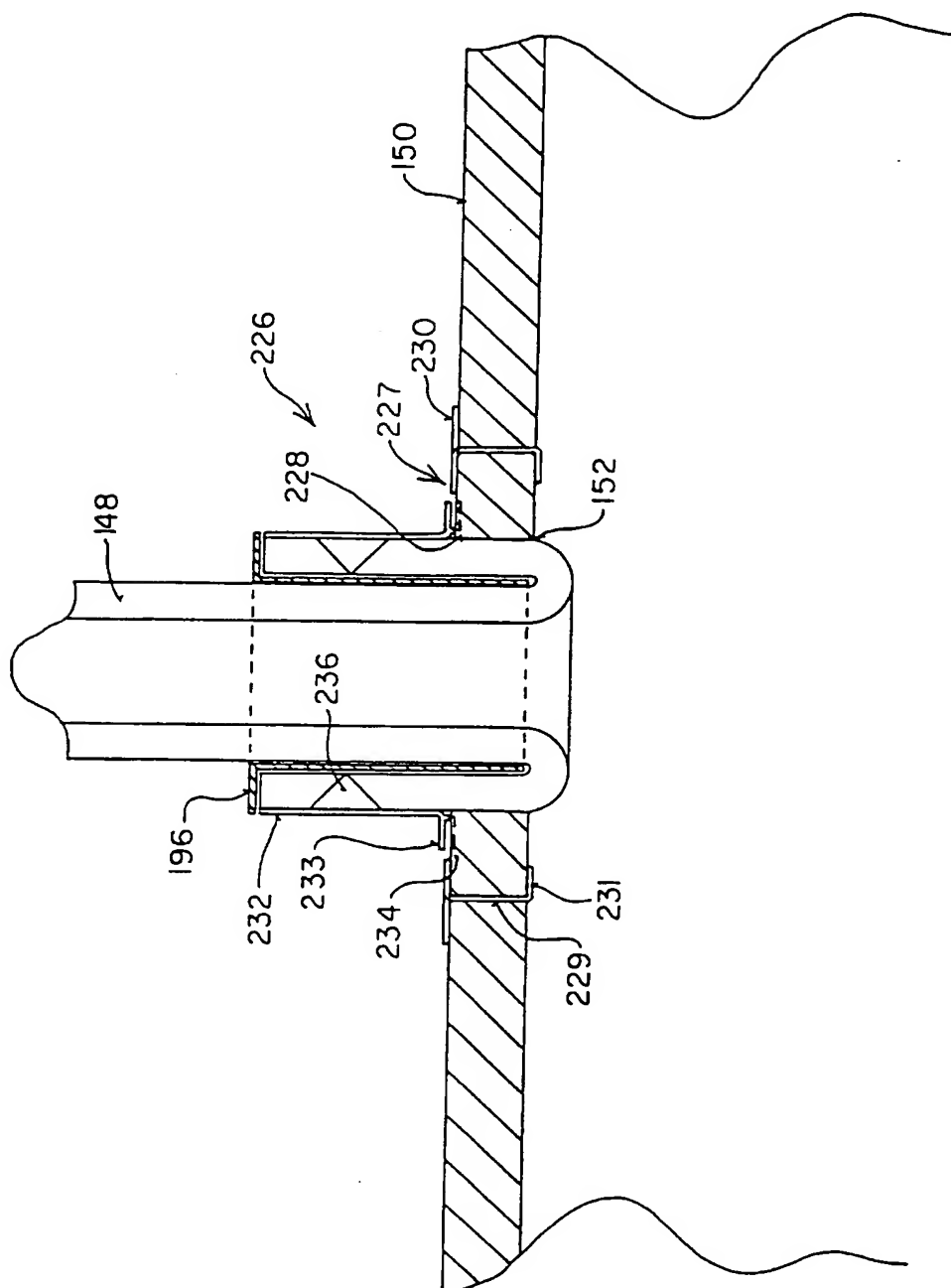


FIG. 19B

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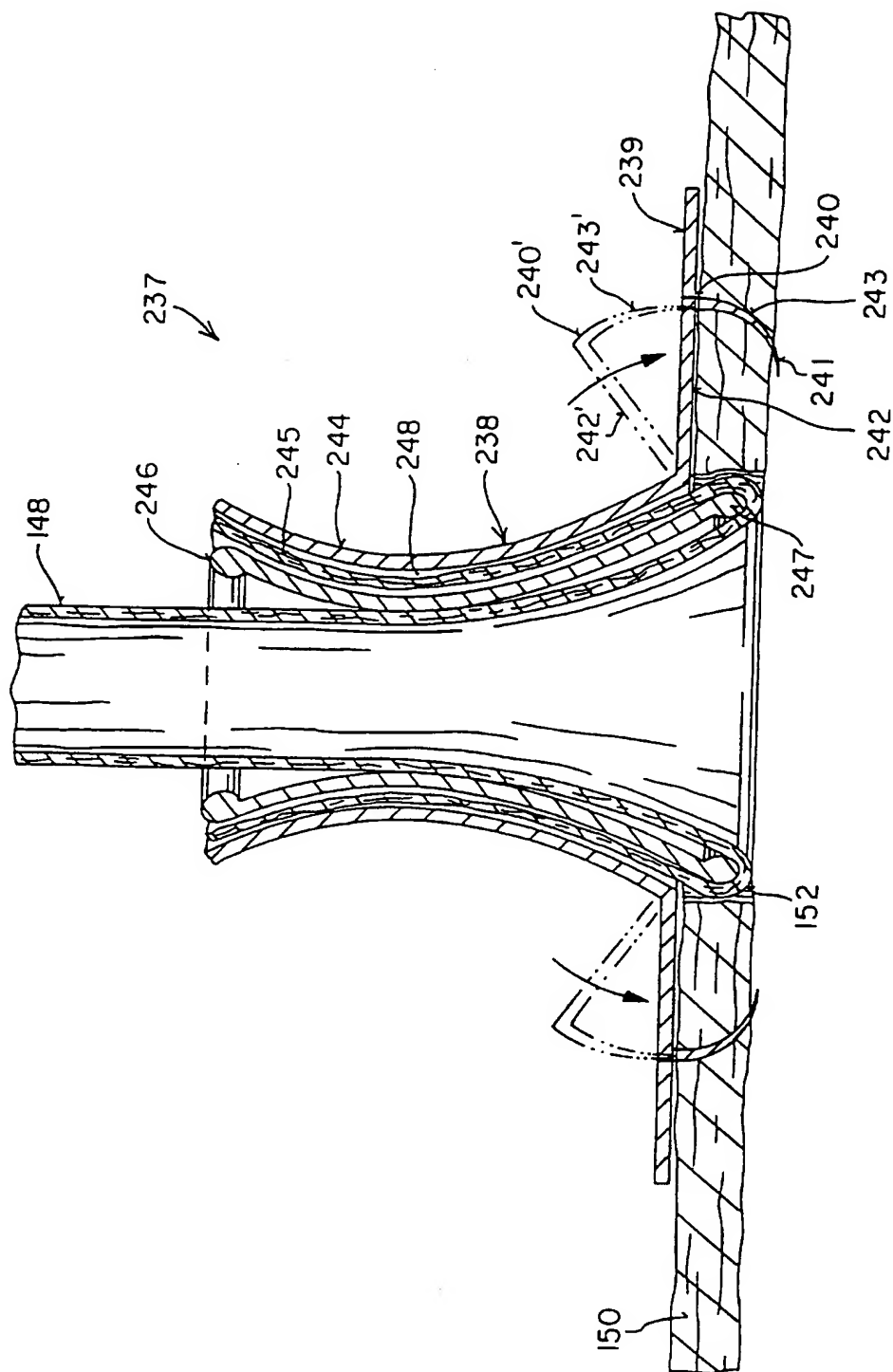


FIG. 20

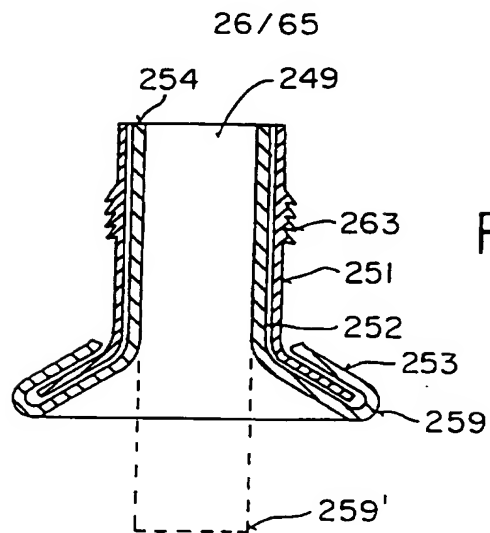


FIG. 21A

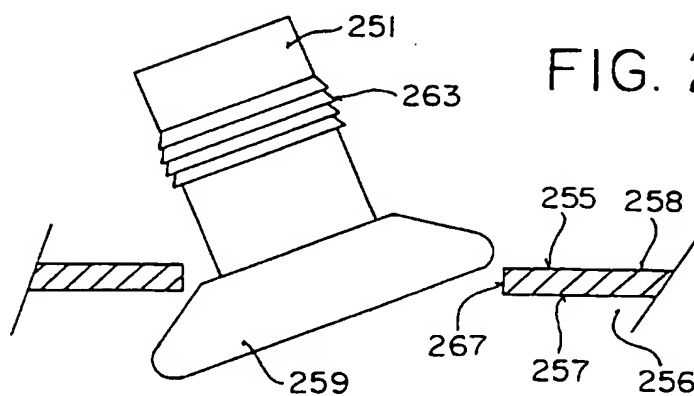


FIG. 21B

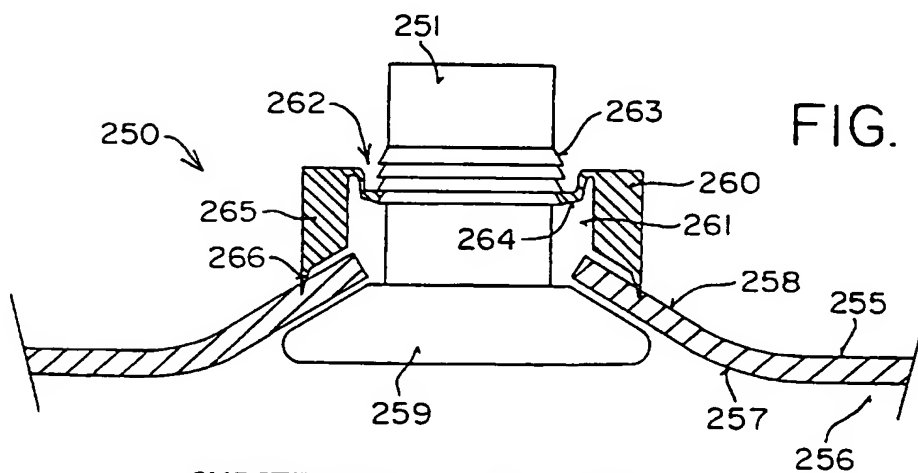


FIG. 21C

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FIG. 22D

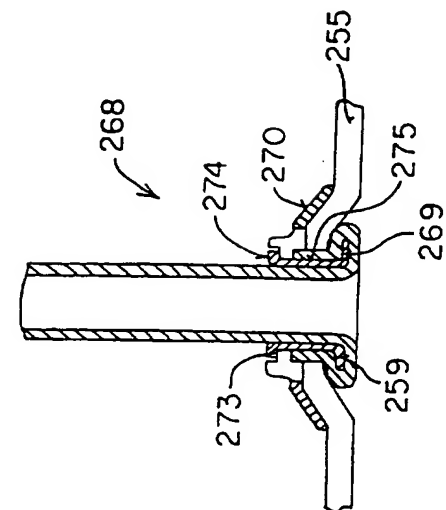
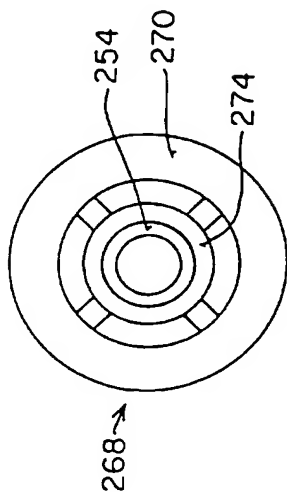


FIG. 22C

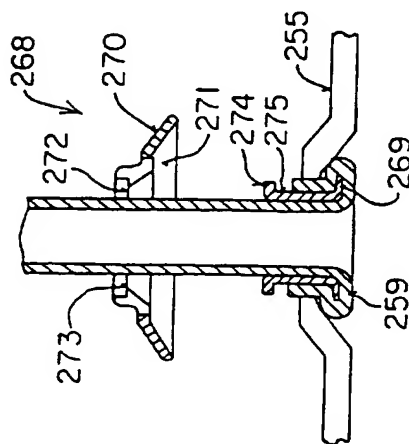


FIG. 22B

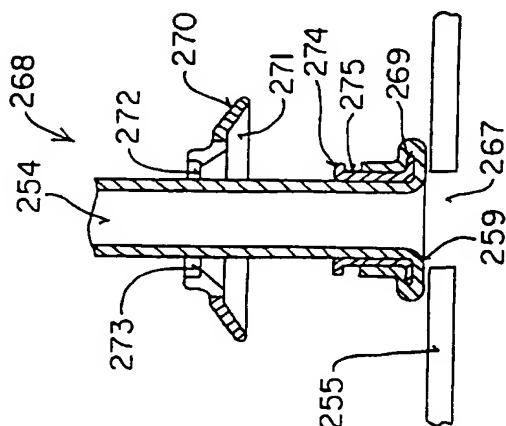


FIG. 22A

FIG. 23D

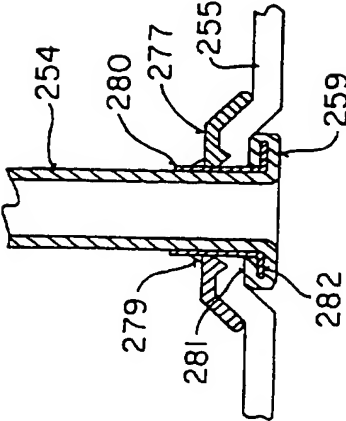
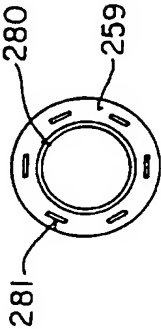


FIG. 23C

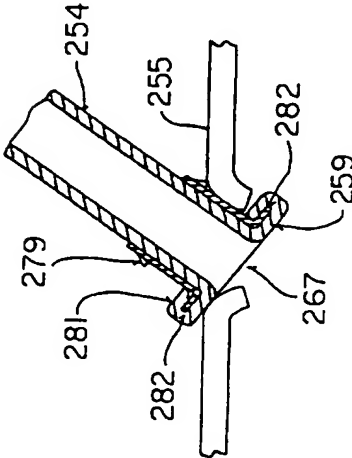


FIG. 23B

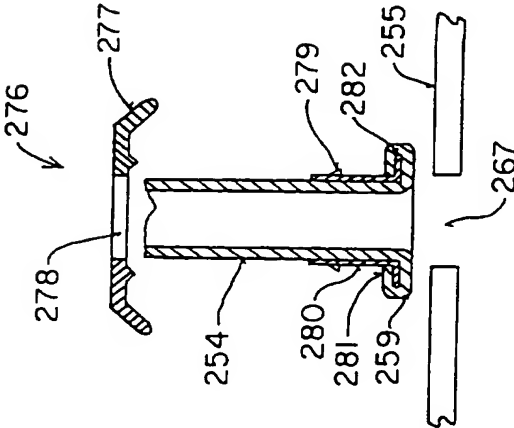


FIG. 23A

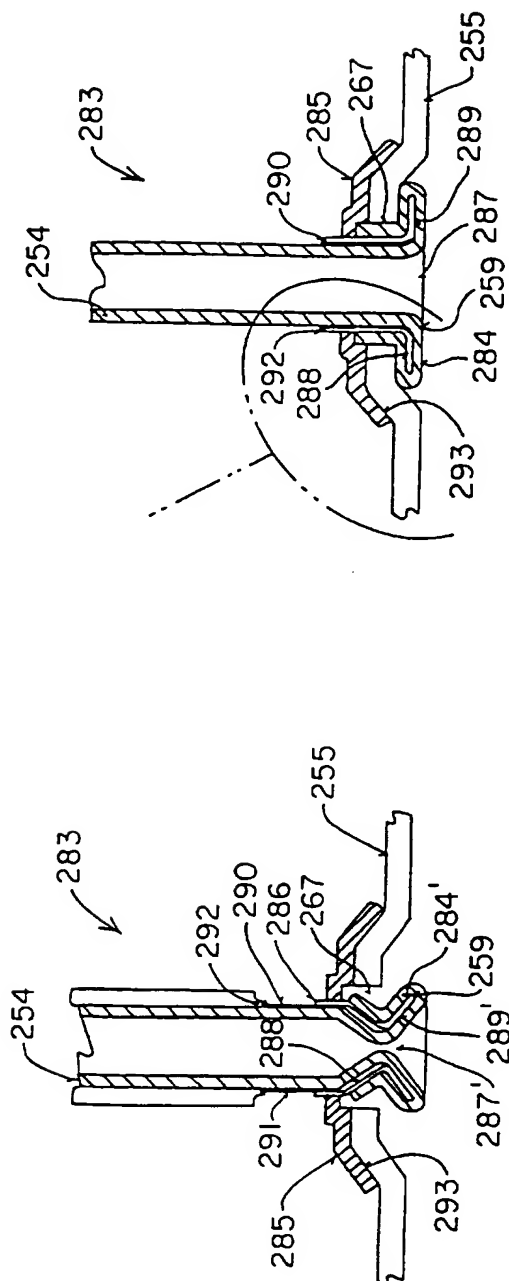


FIG. 24A

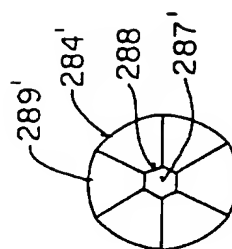


FIG. 24C

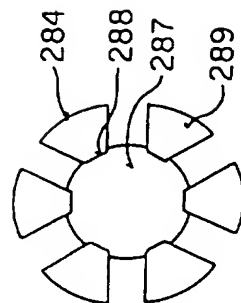


FIG. 24D



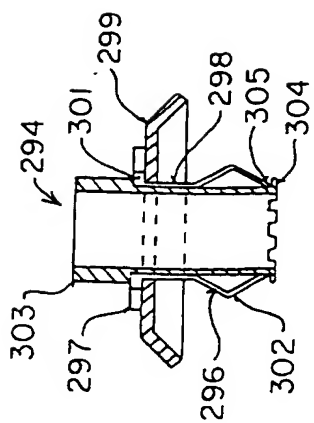


FIG. 25A

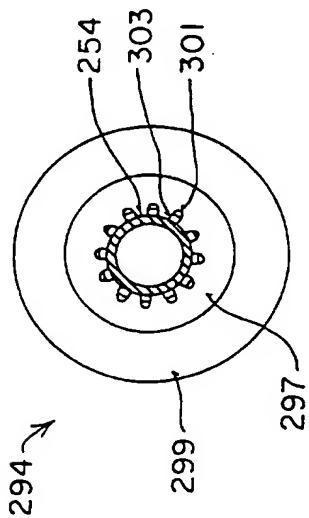


FIG. 25E

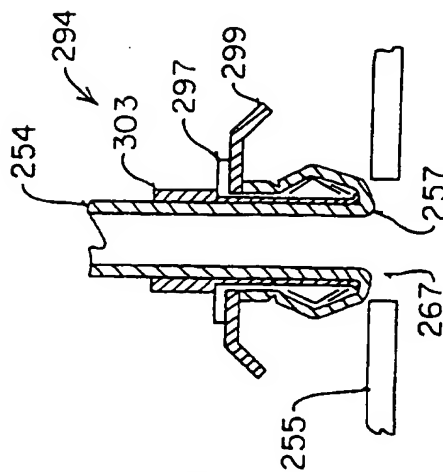


FIG. 25B

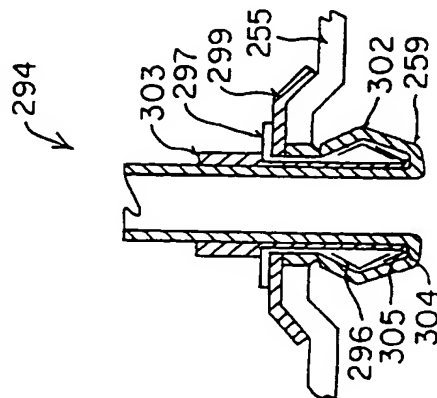


FIG. 25C

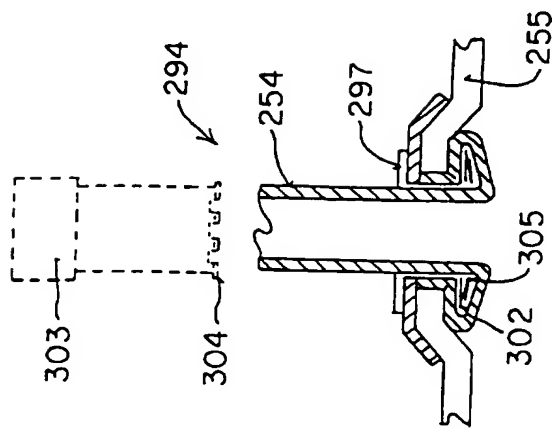


FIG. 25D

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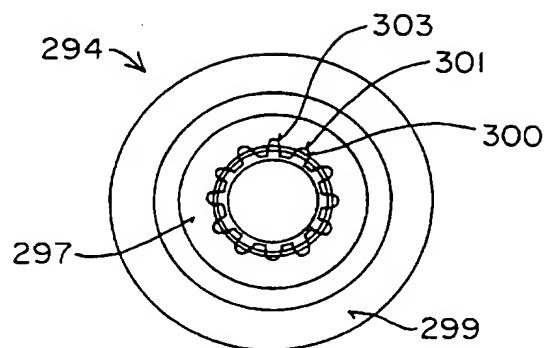


FIG. 25F

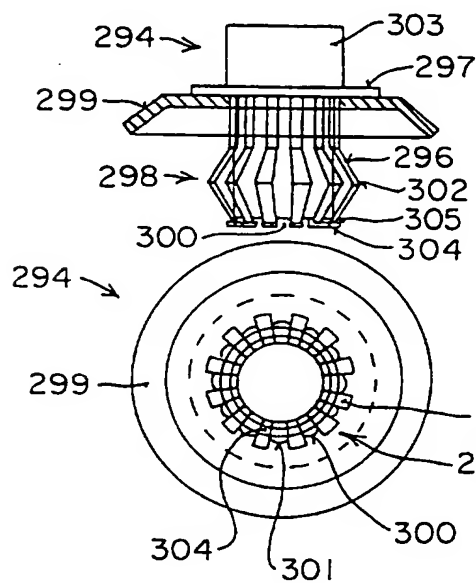


FIG. 25G

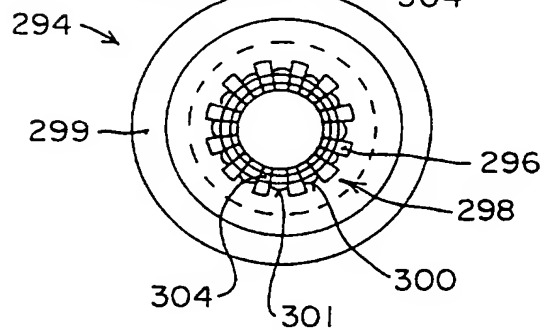


FIG. 25H

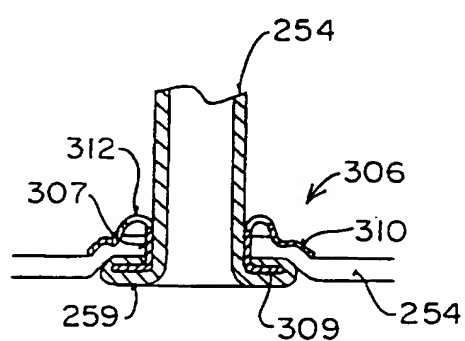
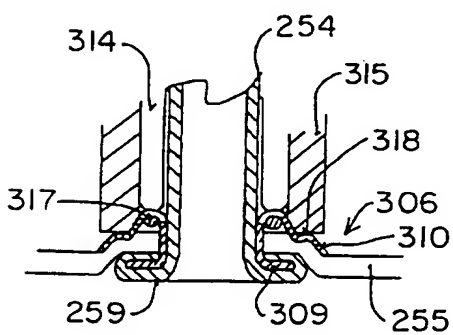
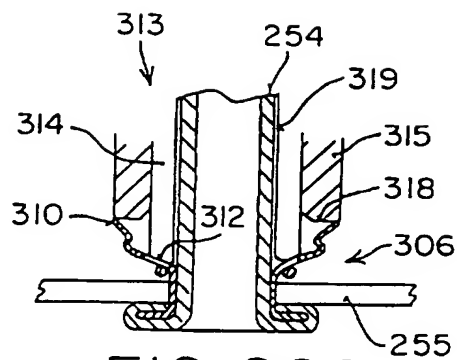
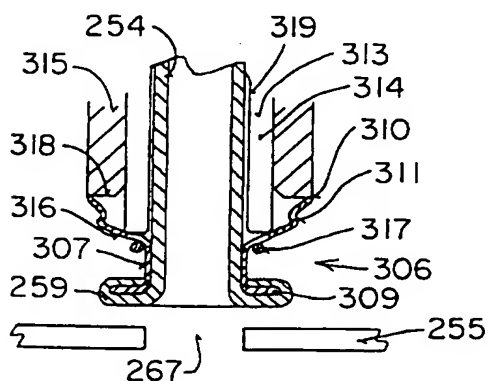
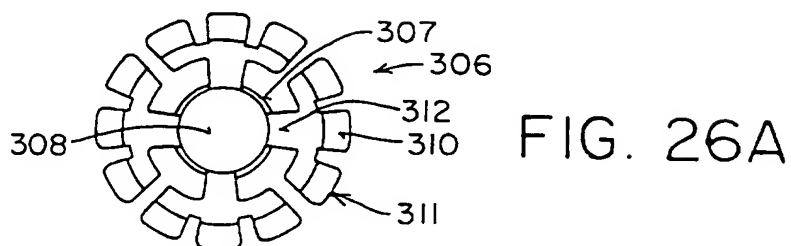


FIG. 26F

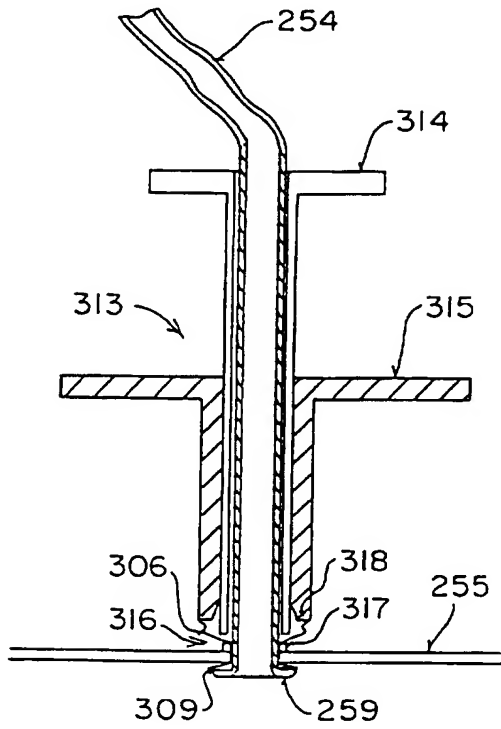


FIG. 26G

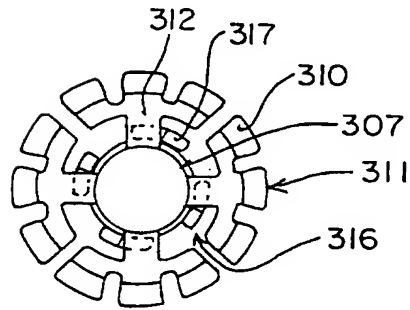
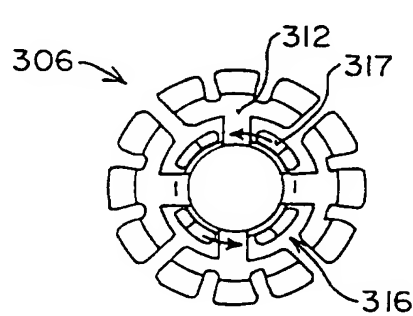
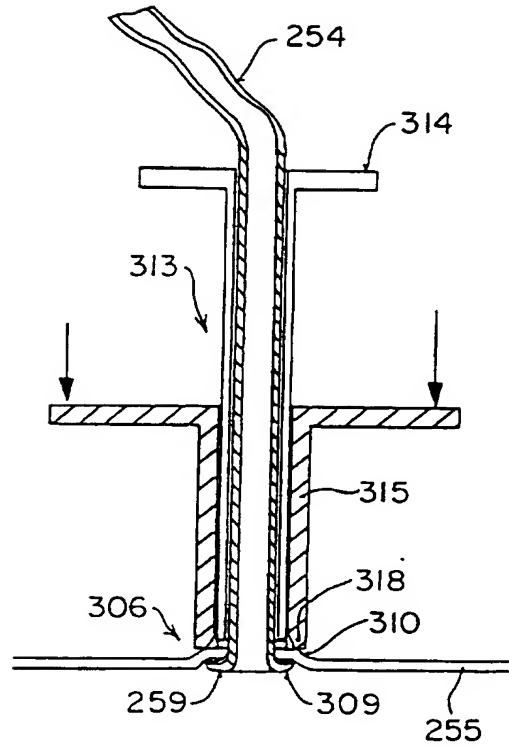


FIG. 26H

FIG. 26I

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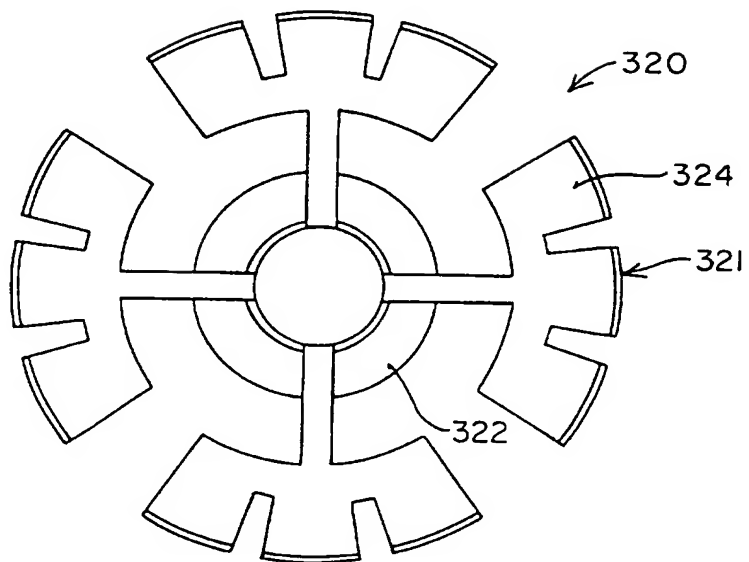


FIG. 27A

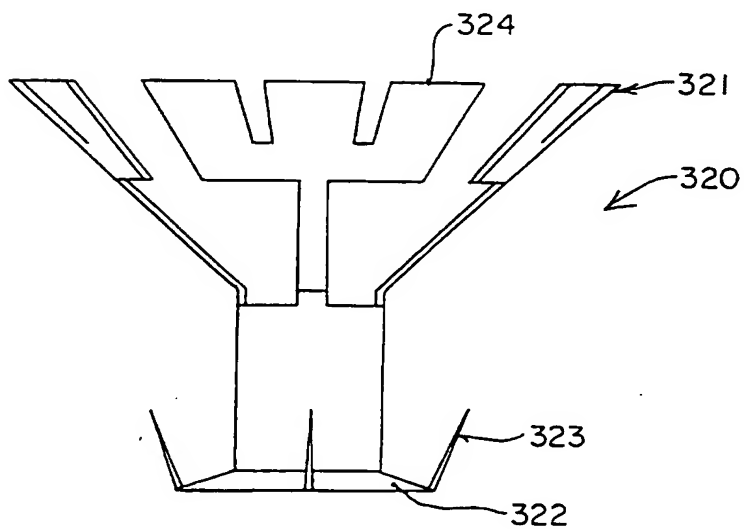


FIG. 27B  
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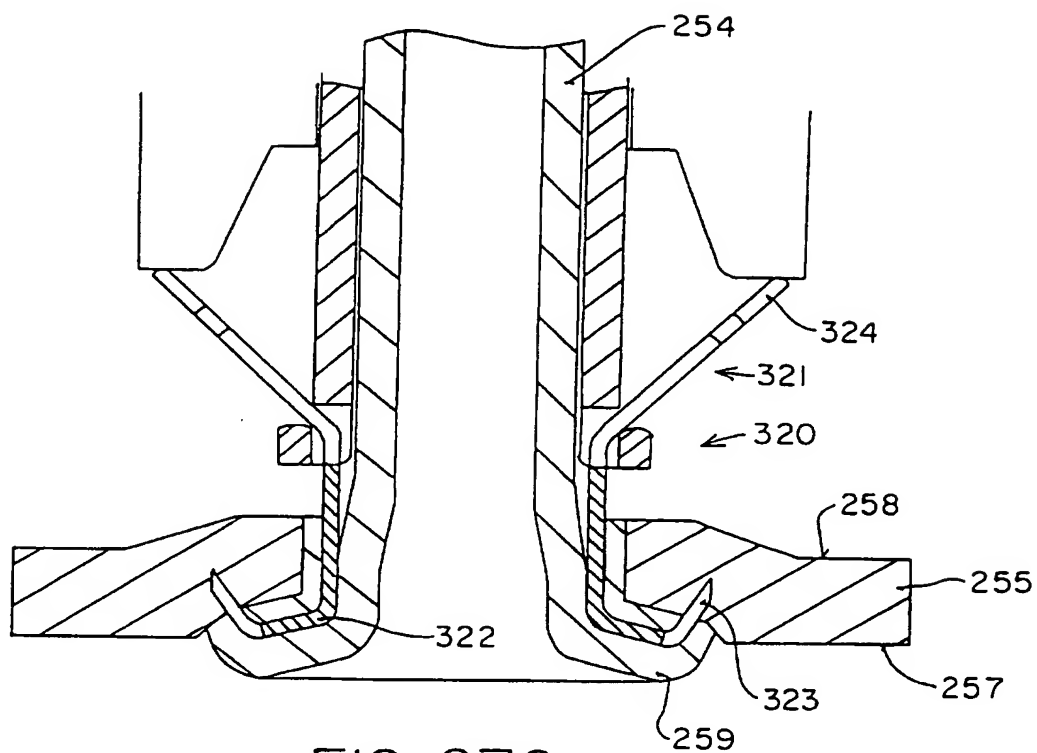


FIG. 27C

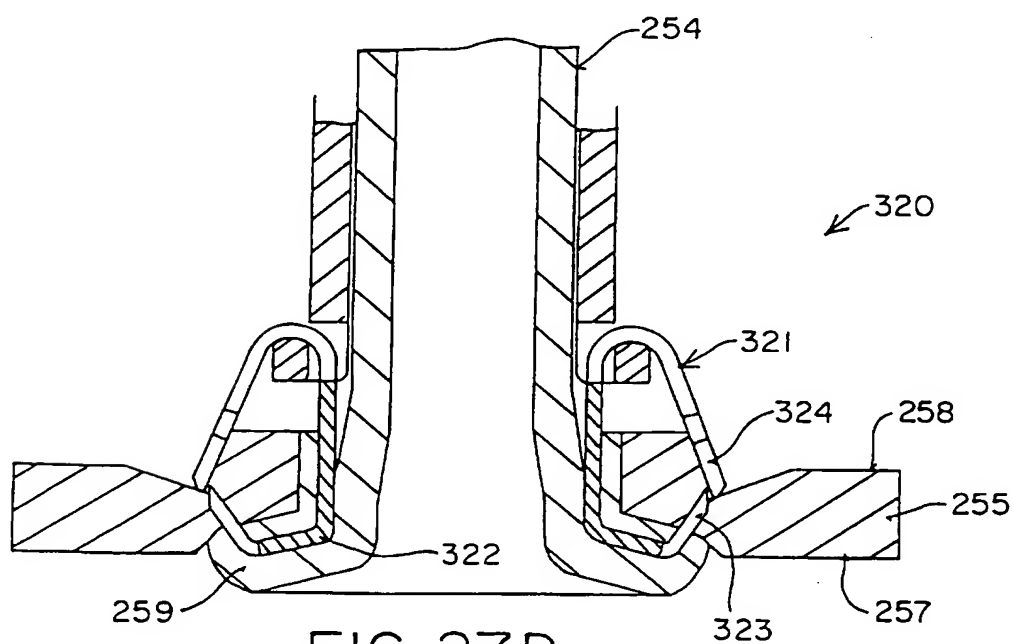


FIG. 27D

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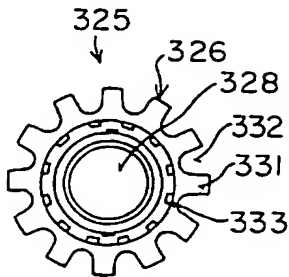


FIG. 28A

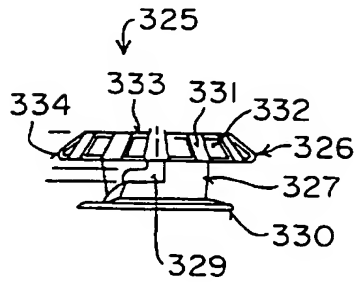


FIG. 28B

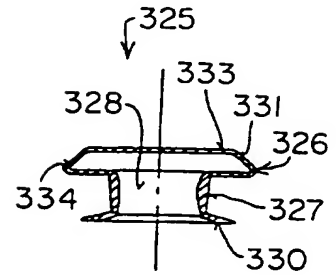


FIG. 28C

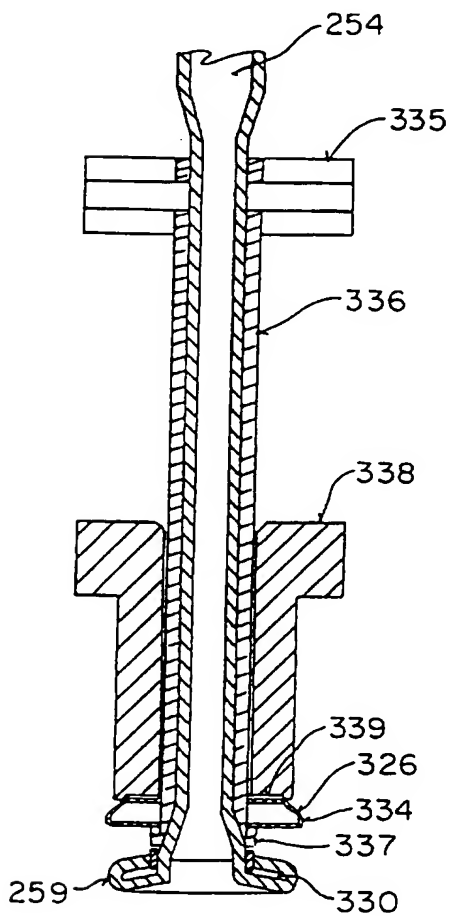


FIG. 28D

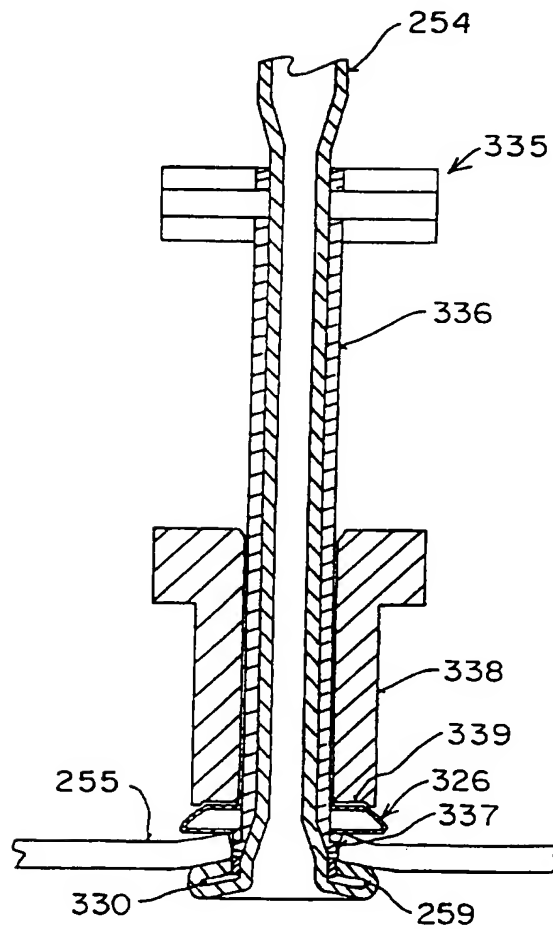


FIG. 28E

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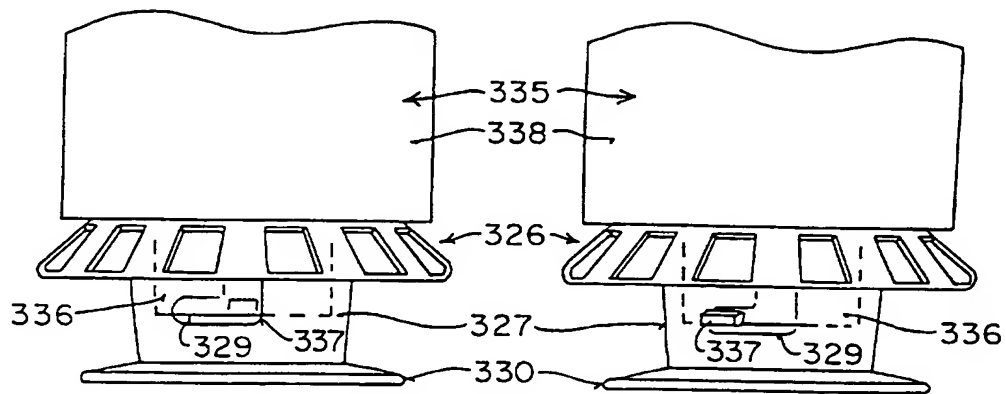


FIG. 28H

FIG. 28I

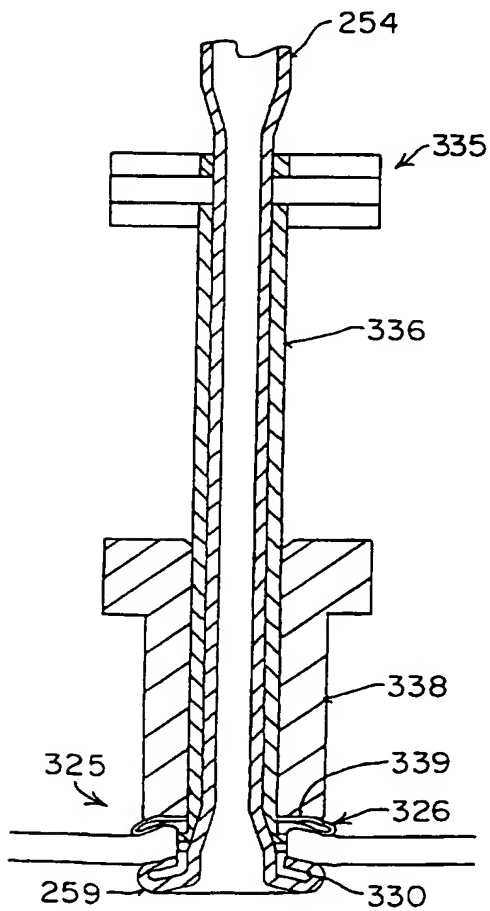


FIG. 28F

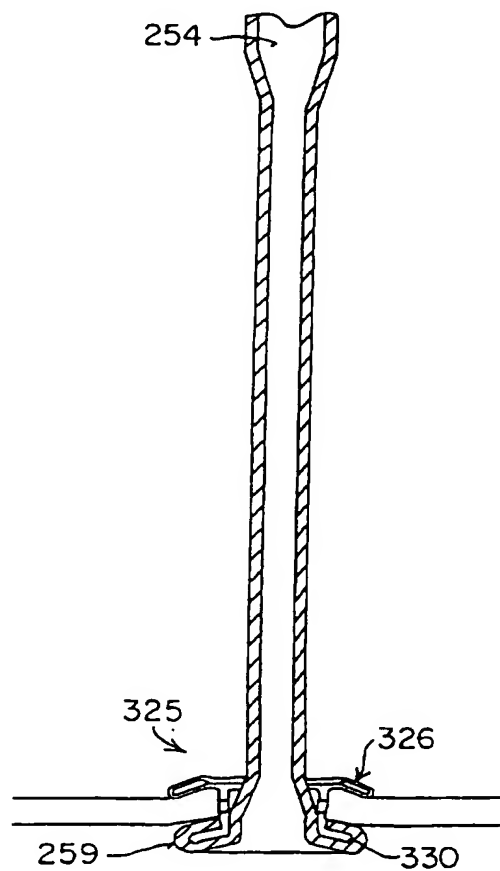


FIG. 28G

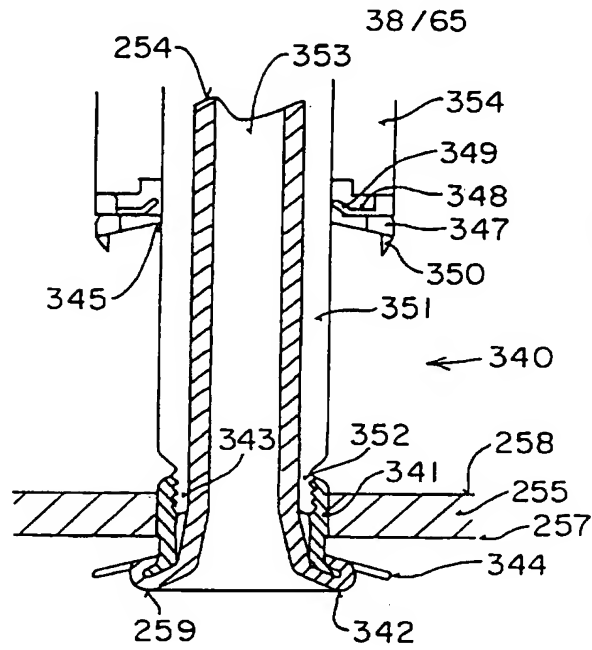


FIG. 29A

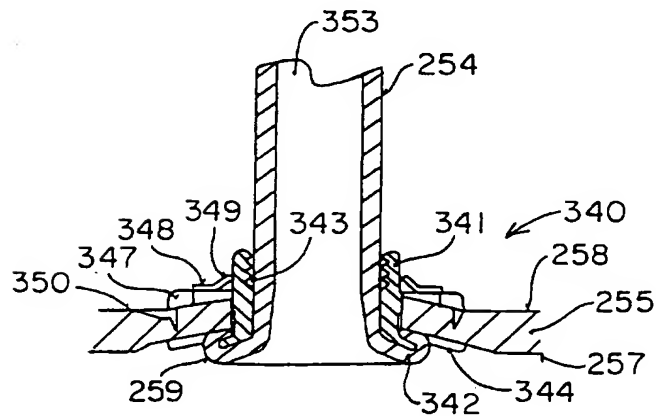


FIG. 29B

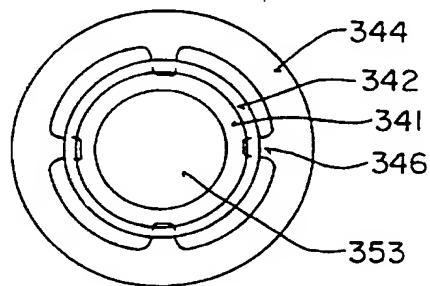


FIG. 29C

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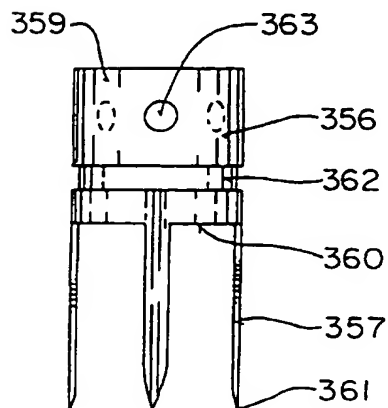


FIG. 30A

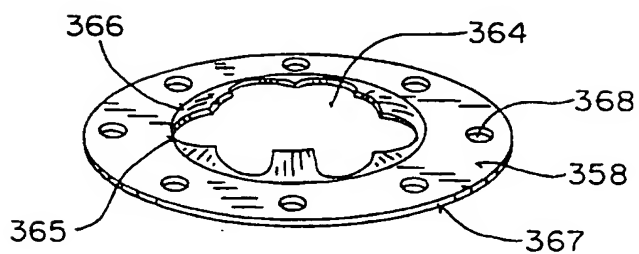


FIG. 30B

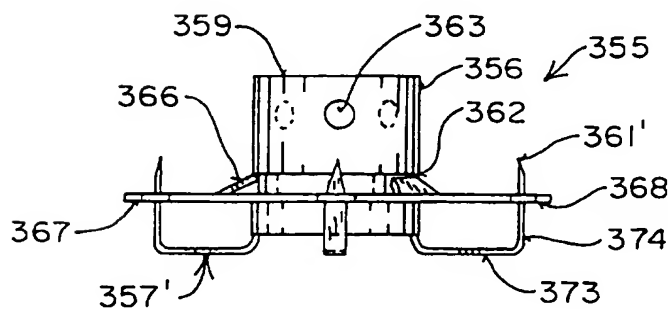


FIG. 30C

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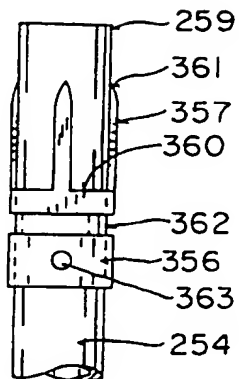


FIG. 30D

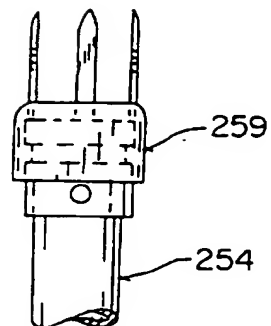


FIG. 30E

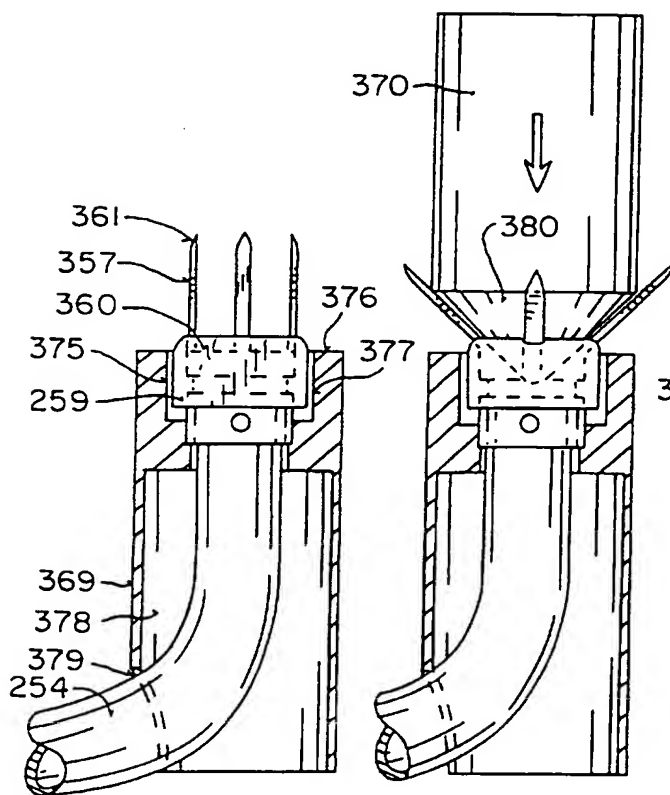


FIG. 30F

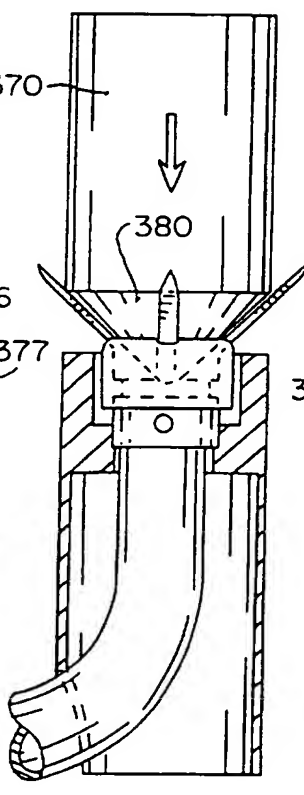


FIG. 30G

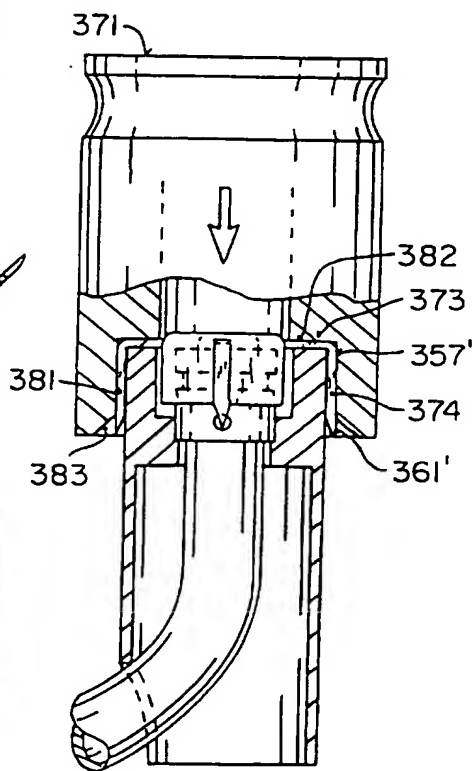


FIG. 30H

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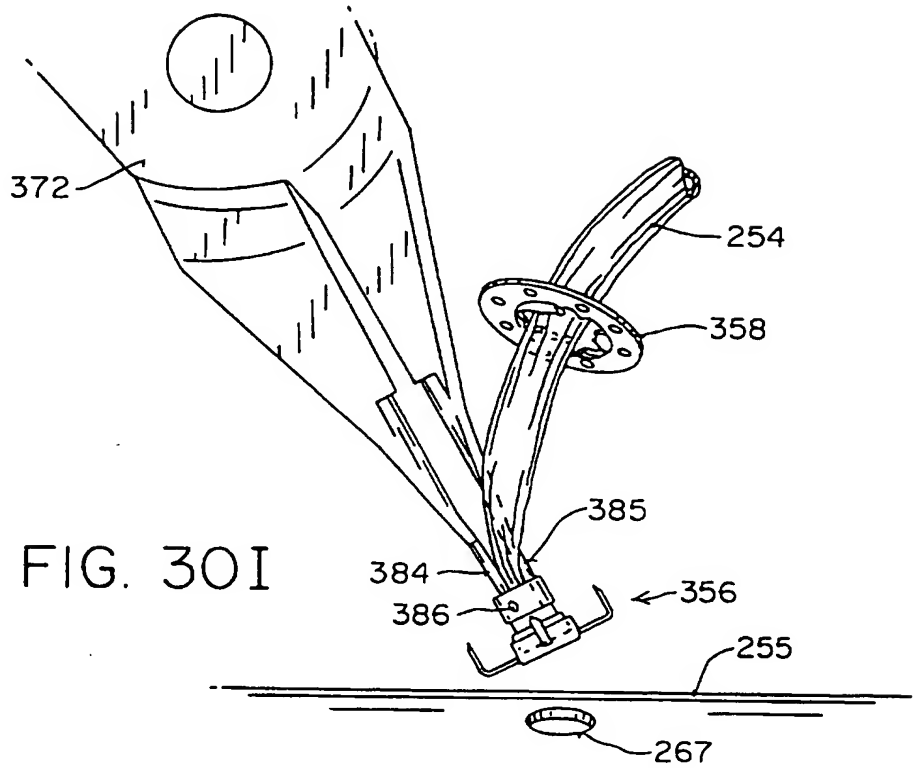


FIG. 30I

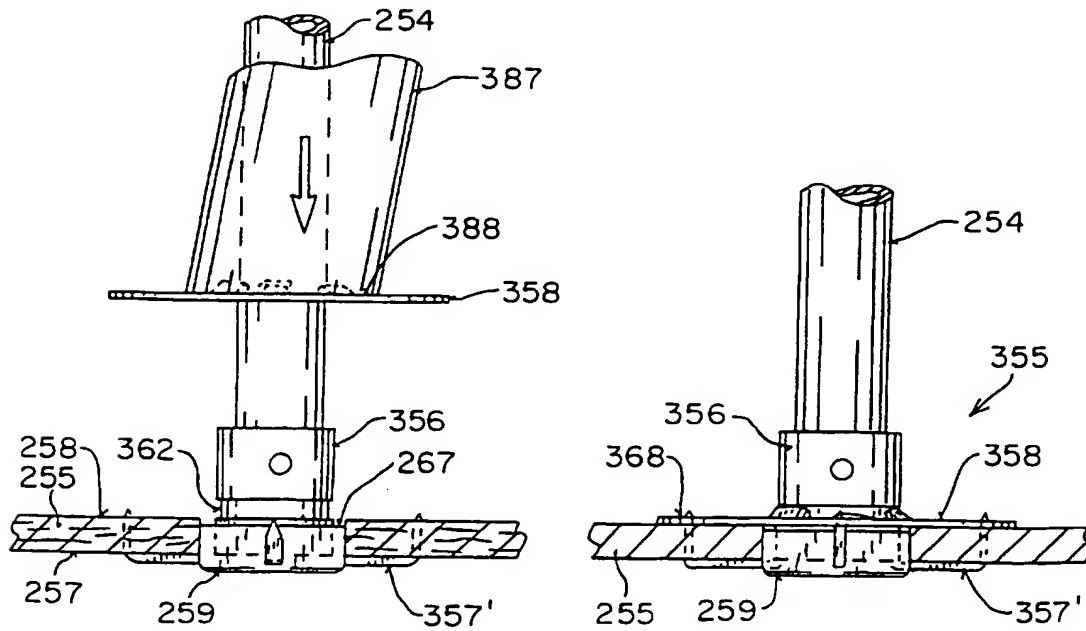


FIG. 30J

FIG. 30K

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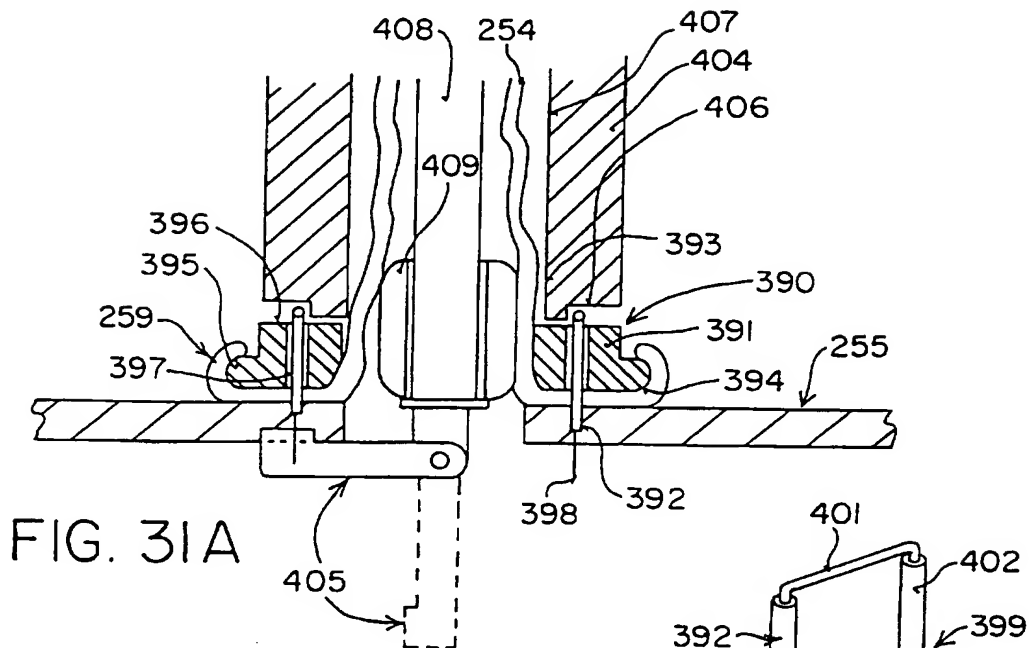


FIG. 31A

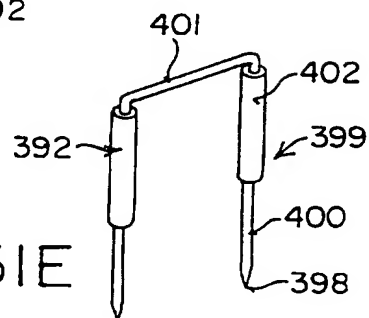


FIG. 31E

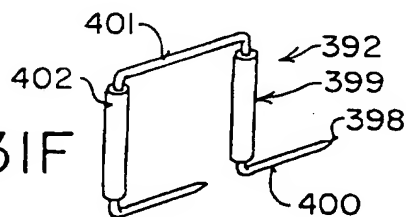


FIG. 31F

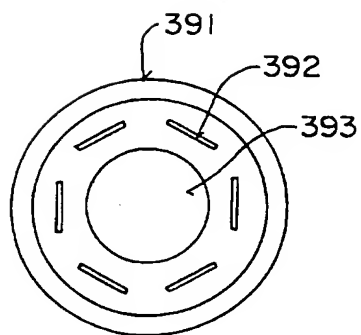


FIG. 31B

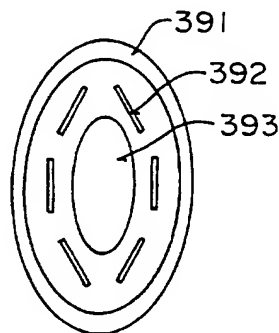


FIG. 31C

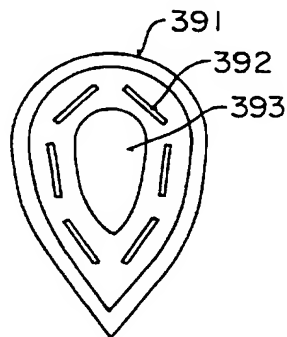


FIG. 31D

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FIG. 32A

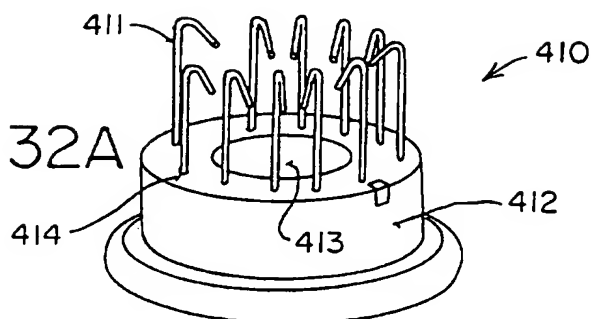


FIG. 32D

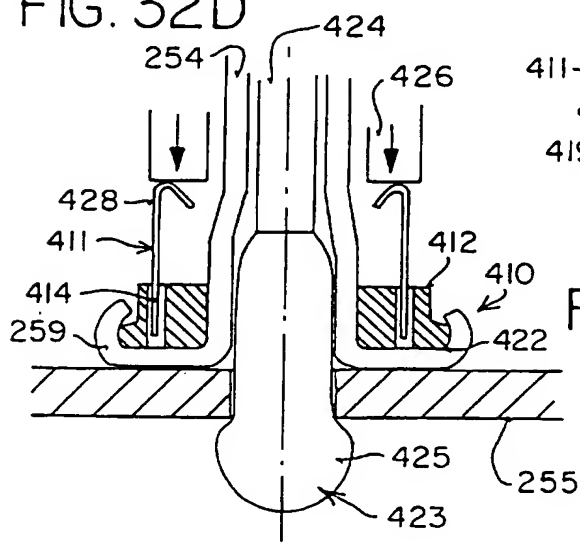


FIG. 32C

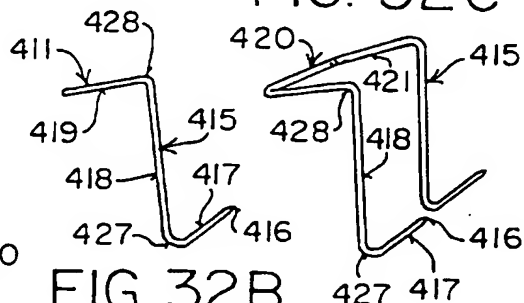


FIG. 32B

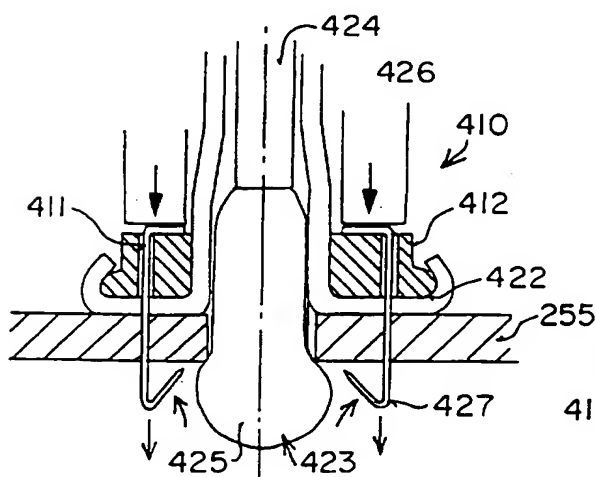
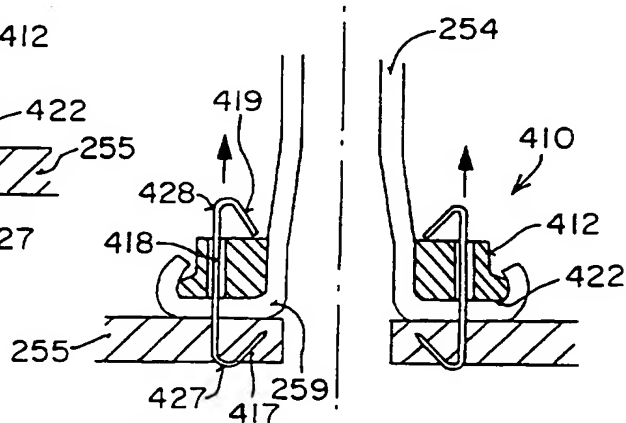
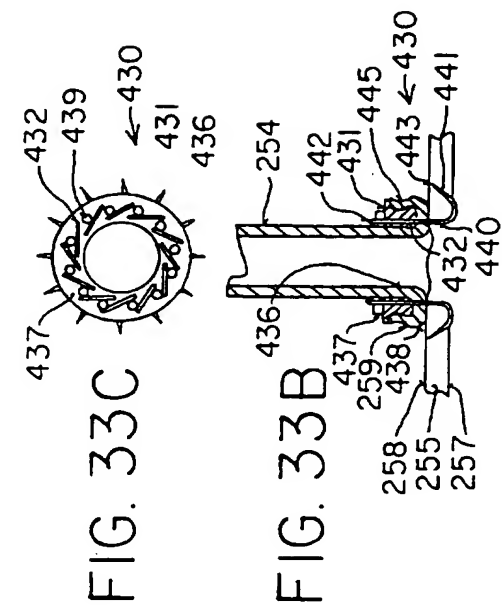


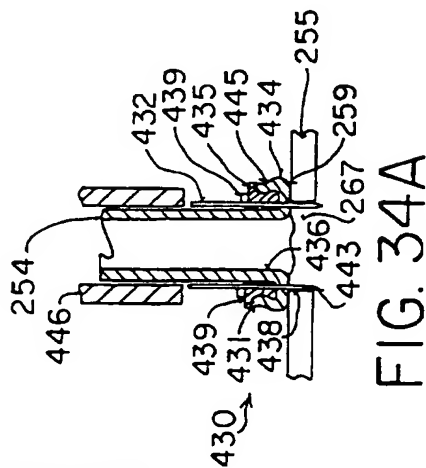
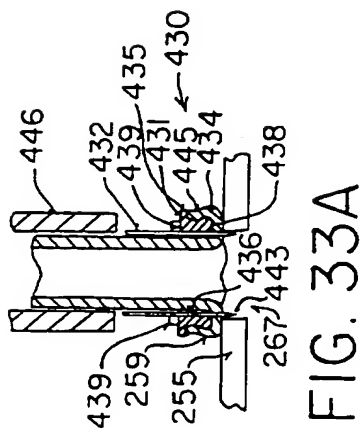
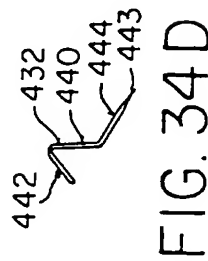
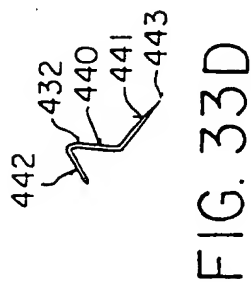
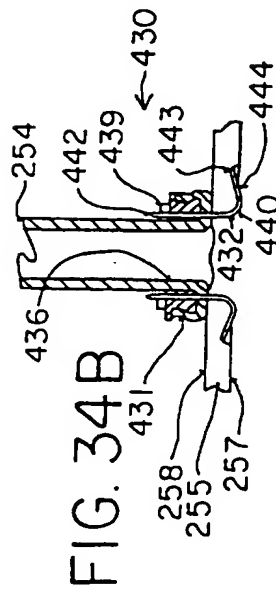
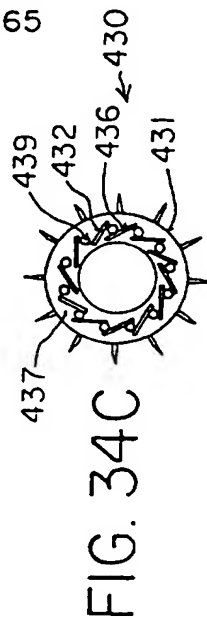
FIG. 32E

FIG. 32F





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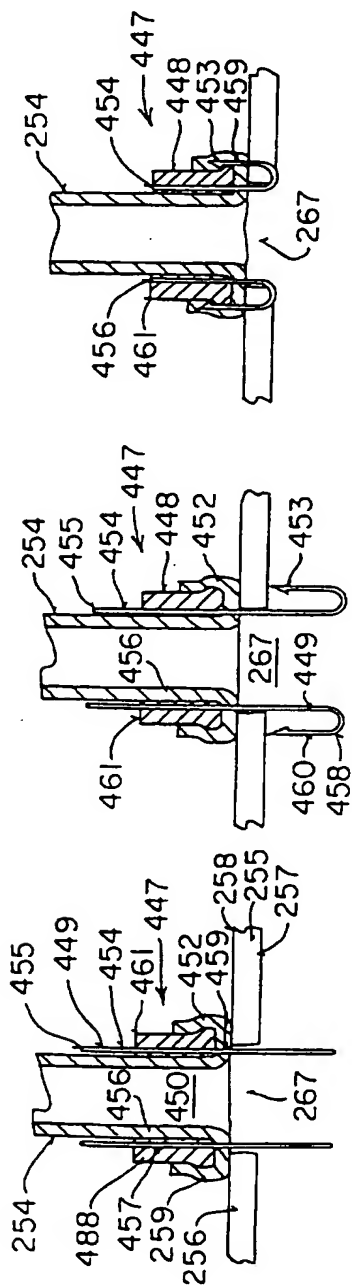


FIG. 35A

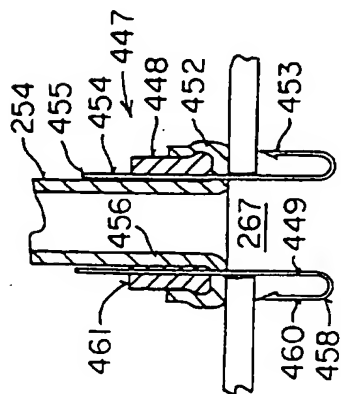


FIG. 35B

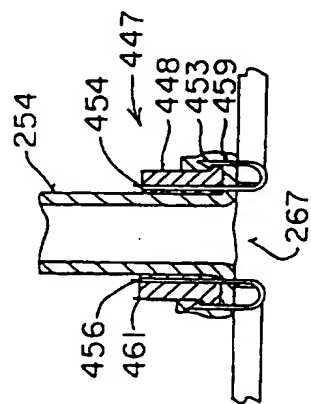


FIG. 35C

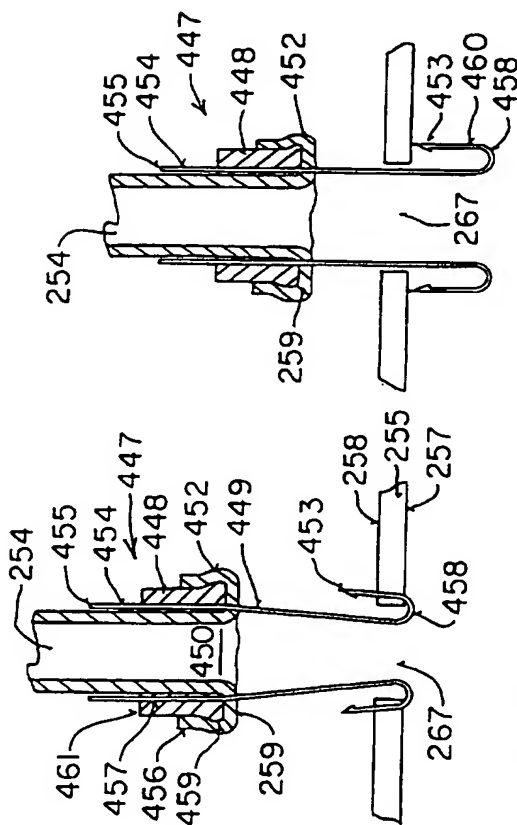


FIG. 35D

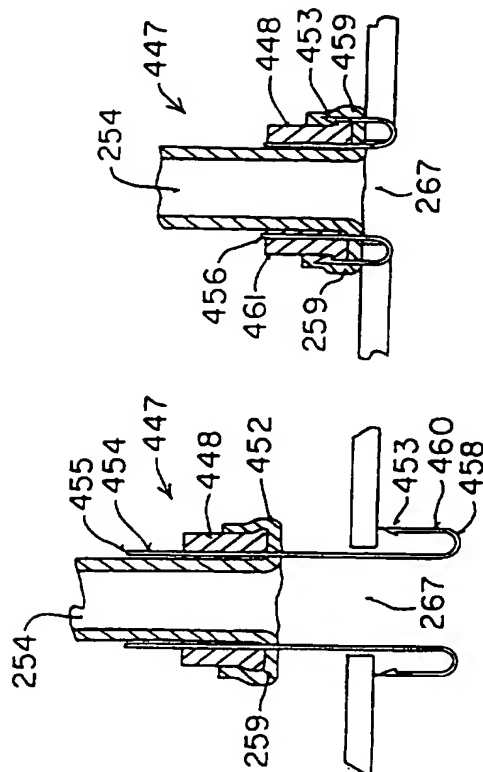


FIG. 35E

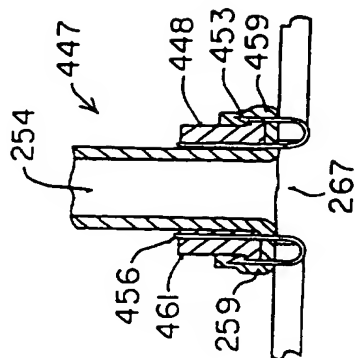


FIG. 35F

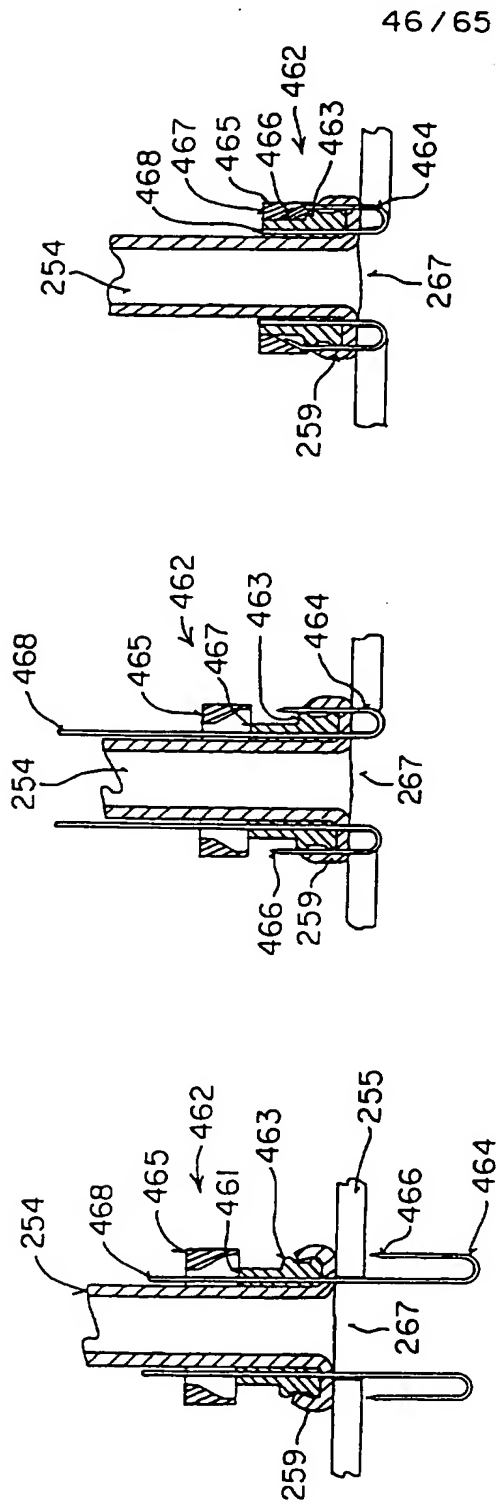
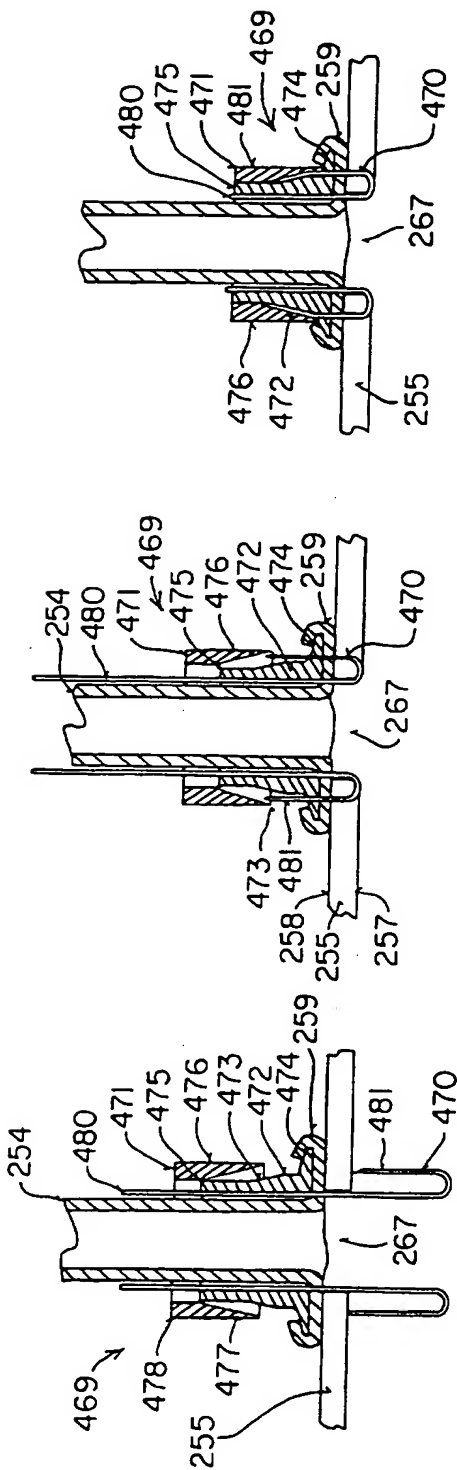


FIG. 36A

FIG. 36B

FIG. 36C

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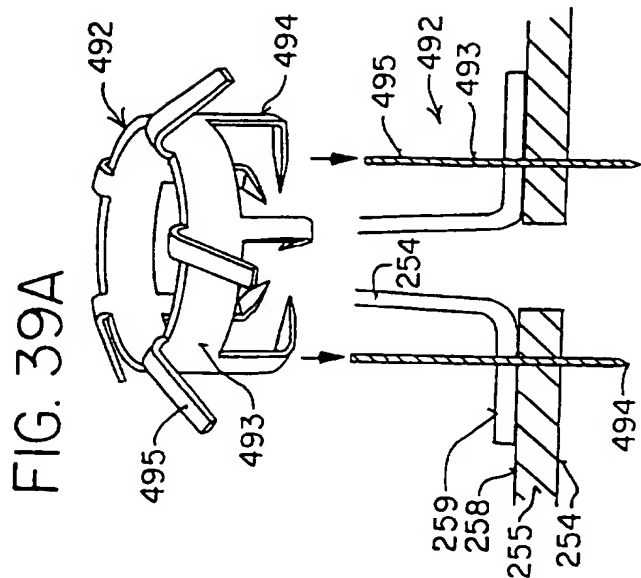
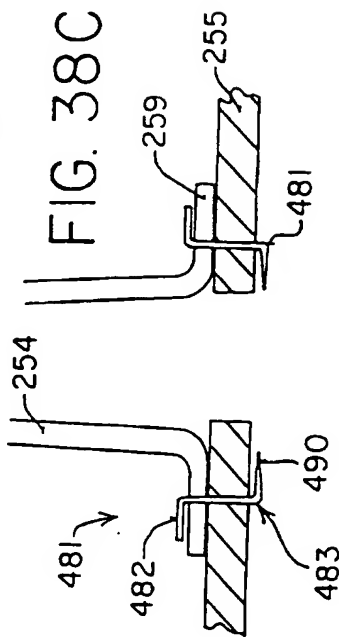
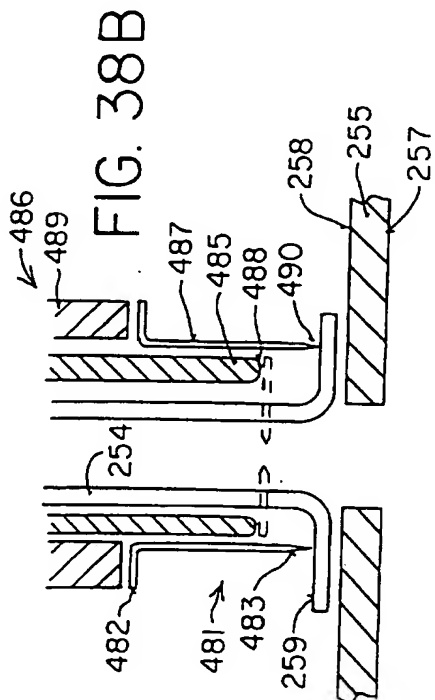
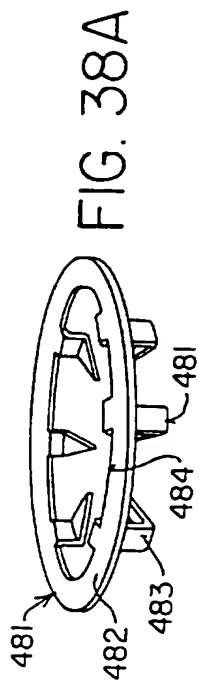
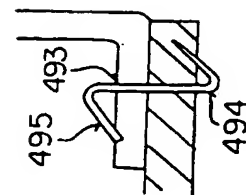


FIG. 39B



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FIG. 40C

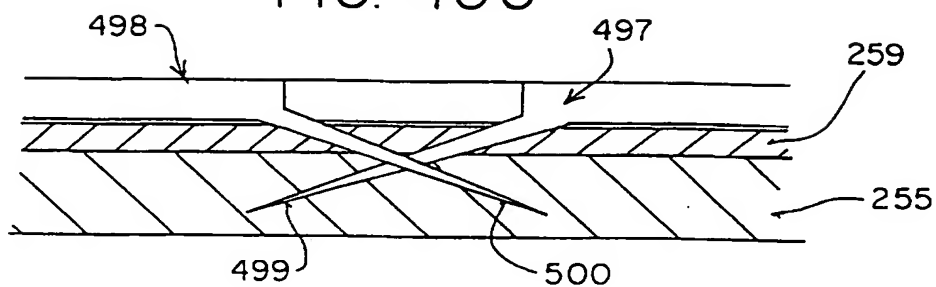


FIG. 40A

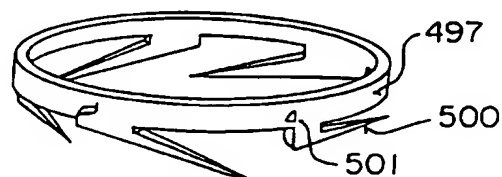


FIG. 40B

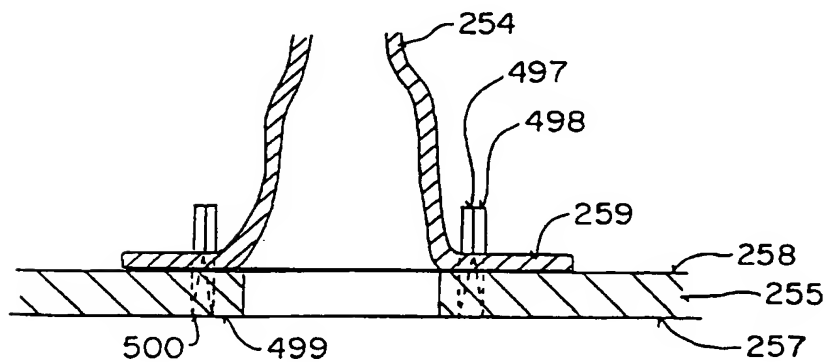
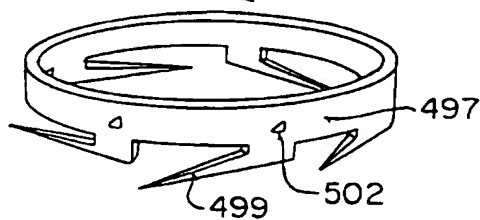


FIG. 40D

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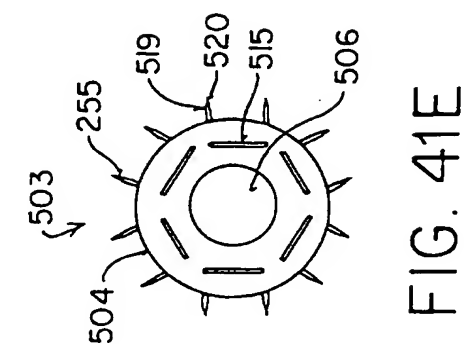


FIG. 41E

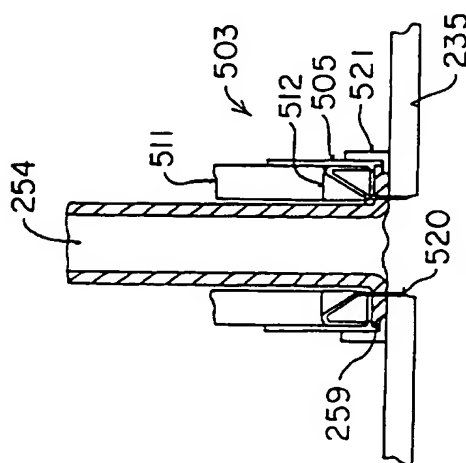


FIG. 41B

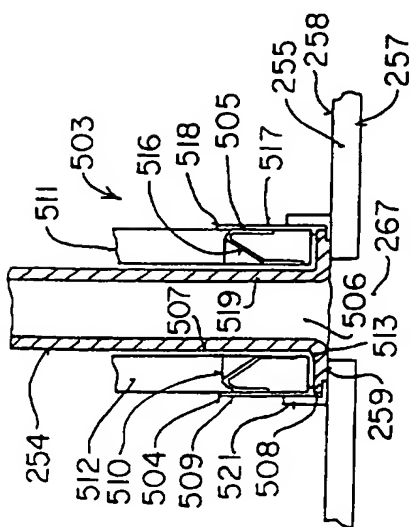


FIG. 41A

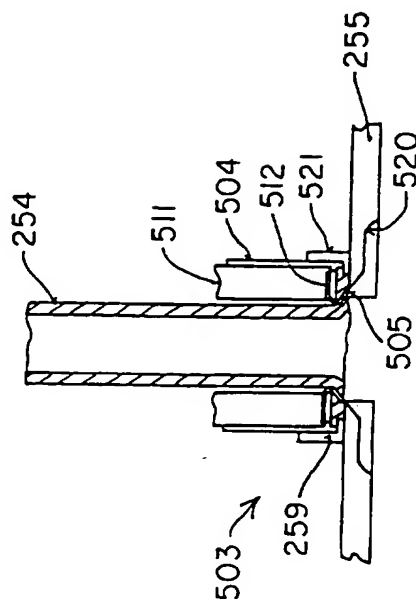


FIG. 41D

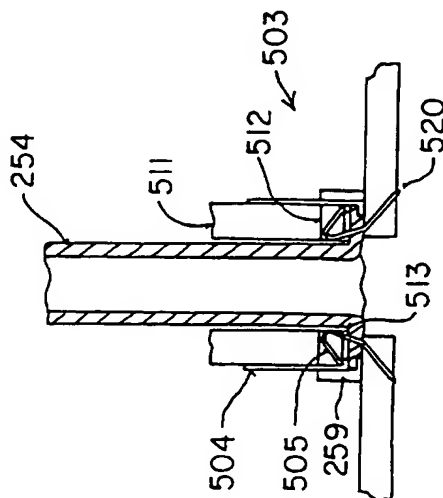


FIG. 41C

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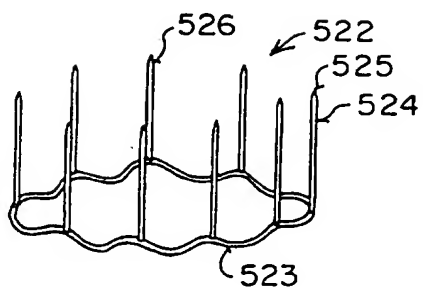


FIG. 42A

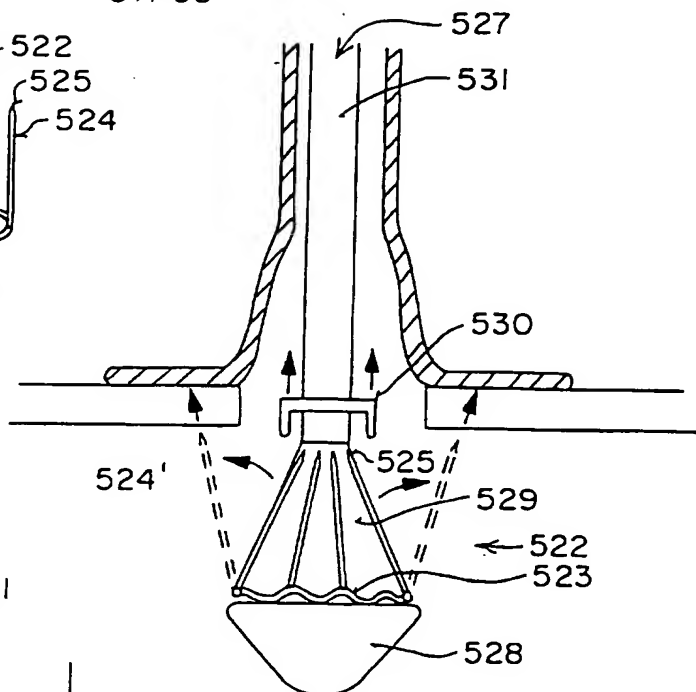


FIG. 42B

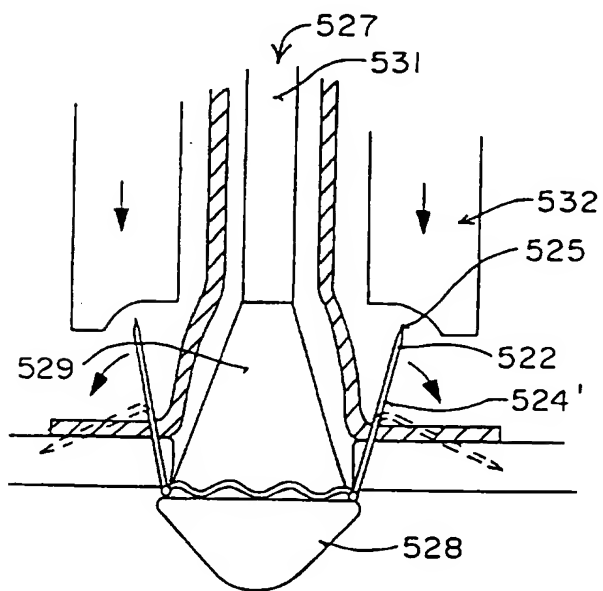


FIG. 42C

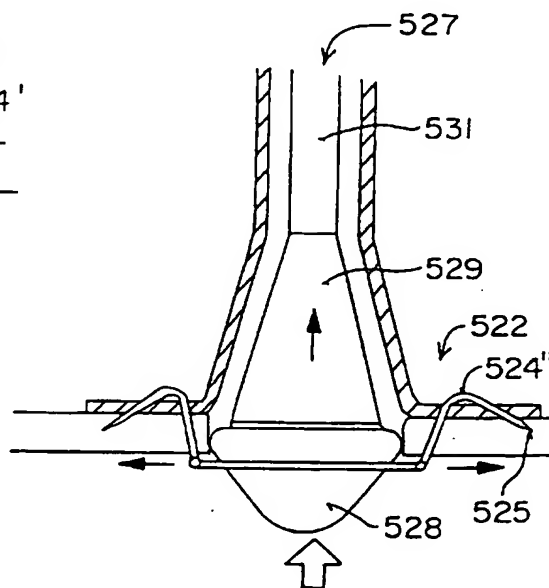


FIG. 42D

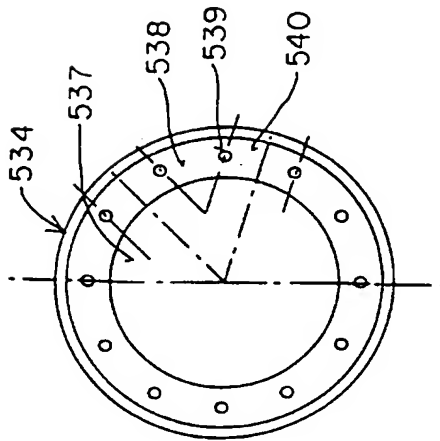


FIG. 43A

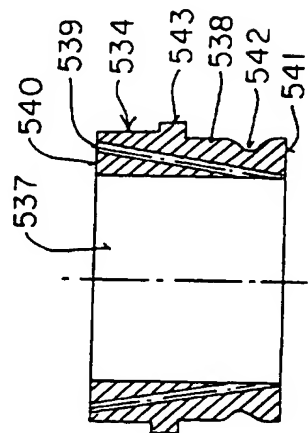


FIG. 43B

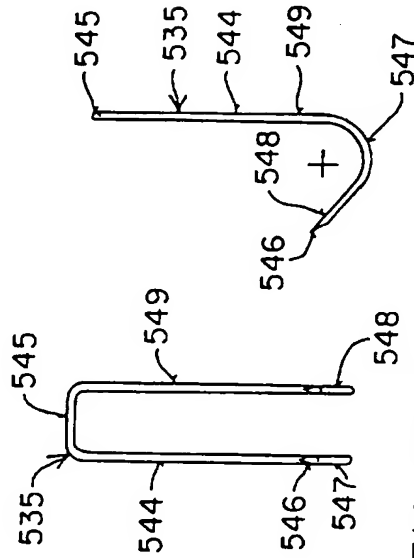


FIG. 44A

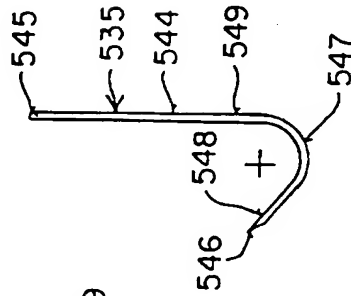


FIG. 44B

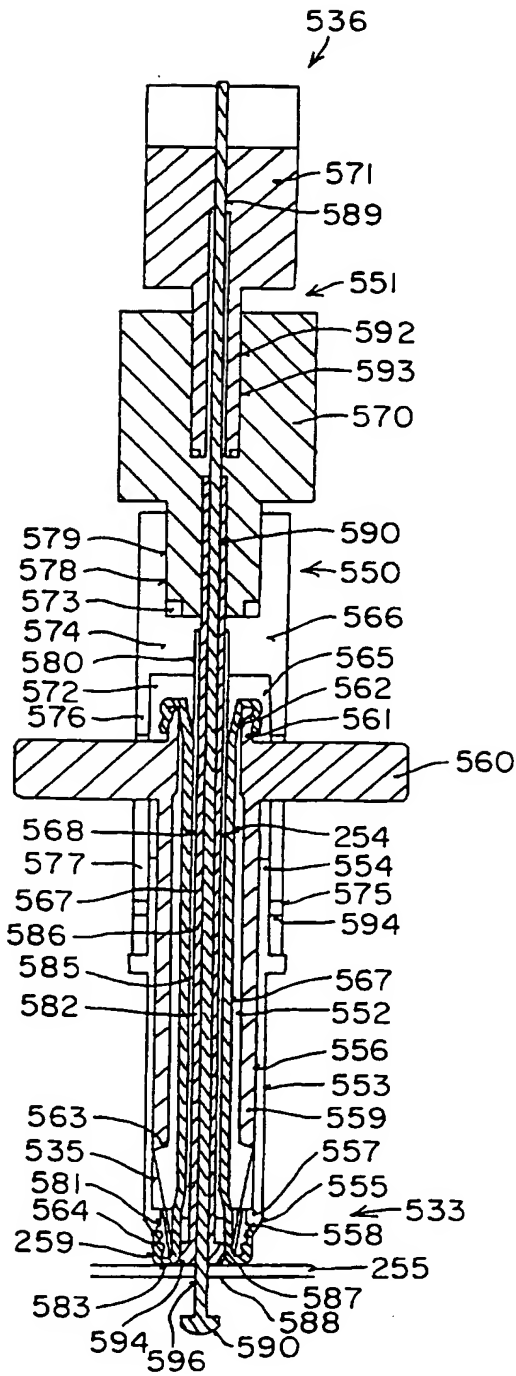


FIG. 45A

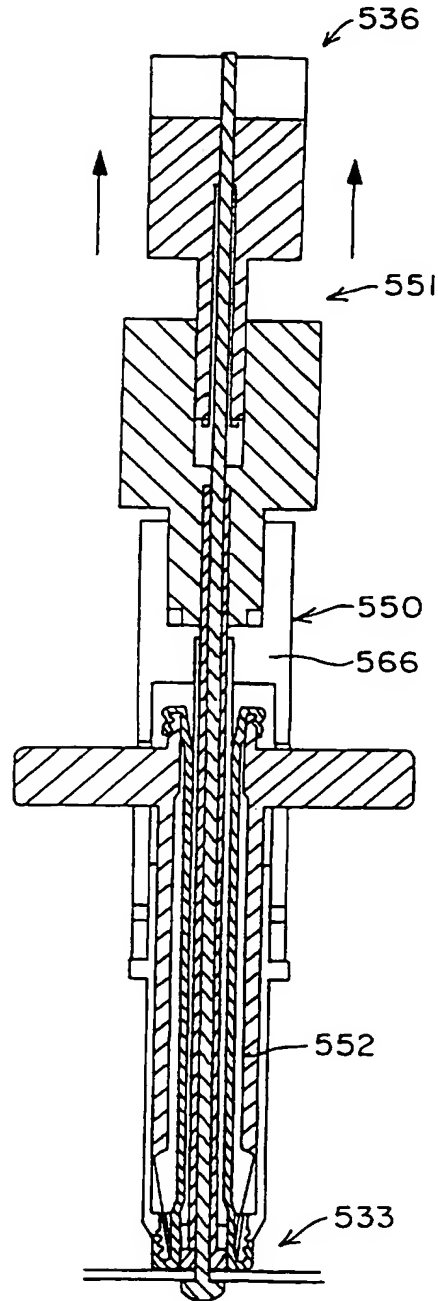


FIG. 45B

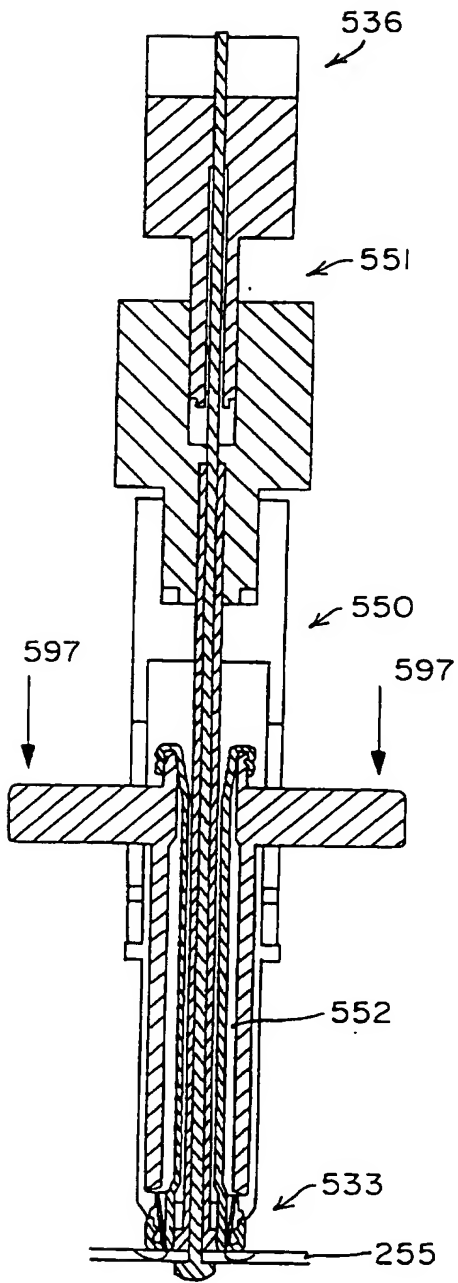


FIG. 45C

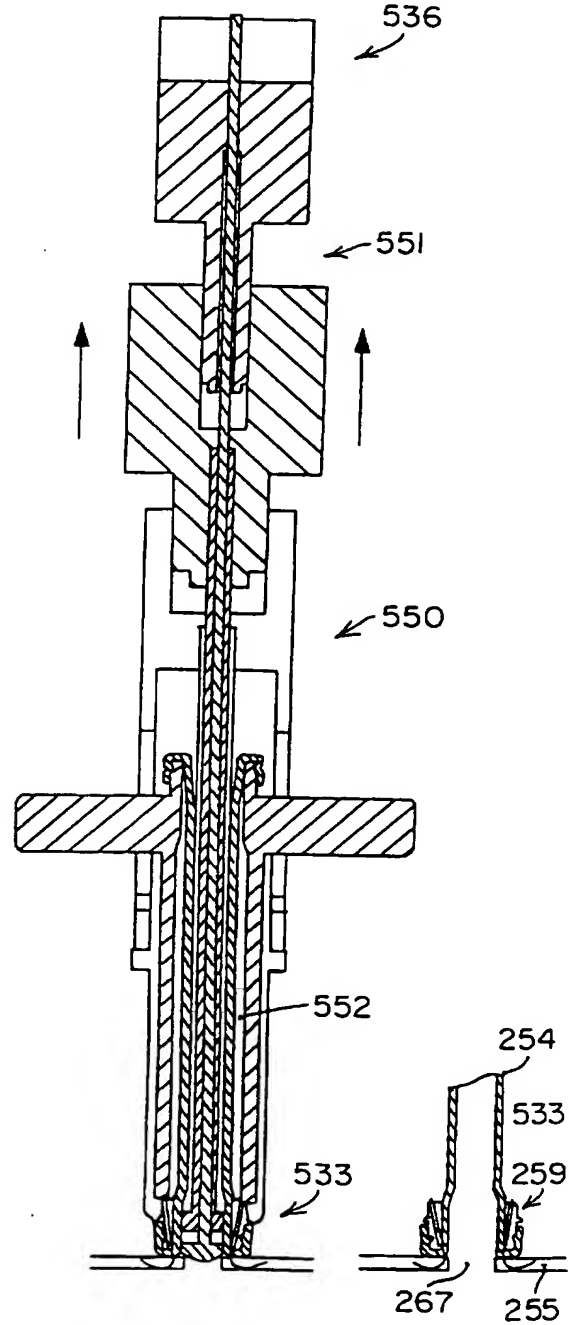


FIG. 45D

FIG. 45E

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FIG. 46C

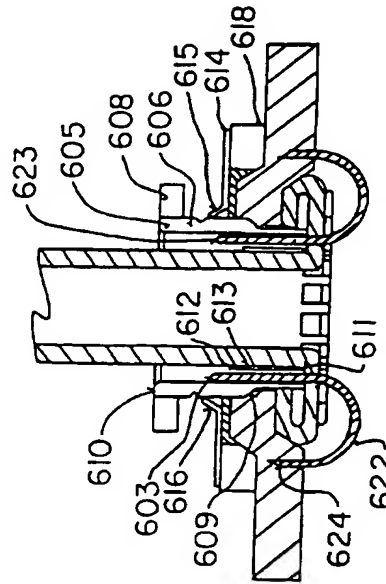
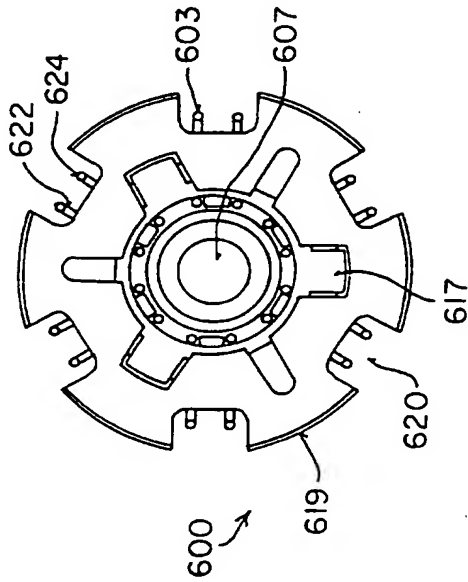


FIG. 46B

FIG. 46D

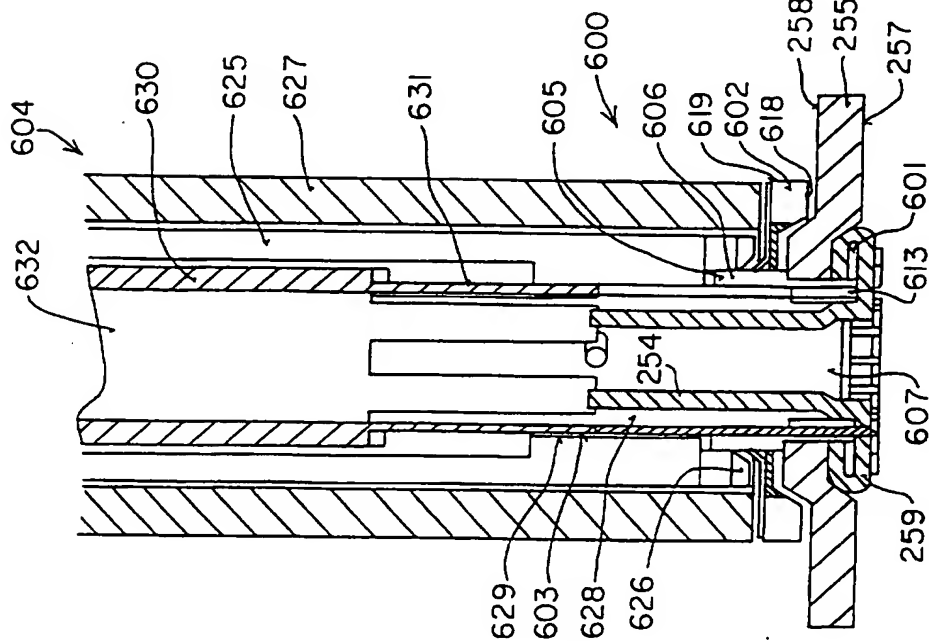
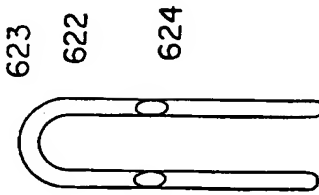


FIG. 46A

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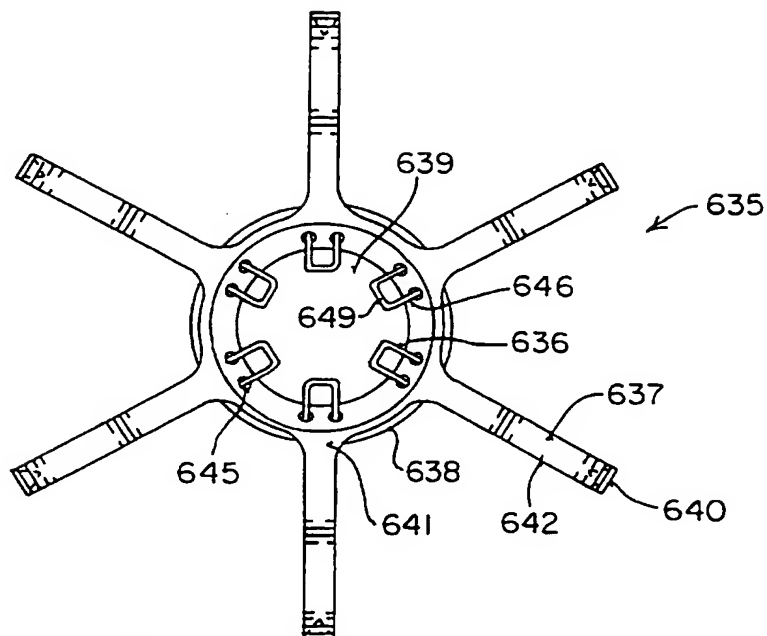


FIG. 47A

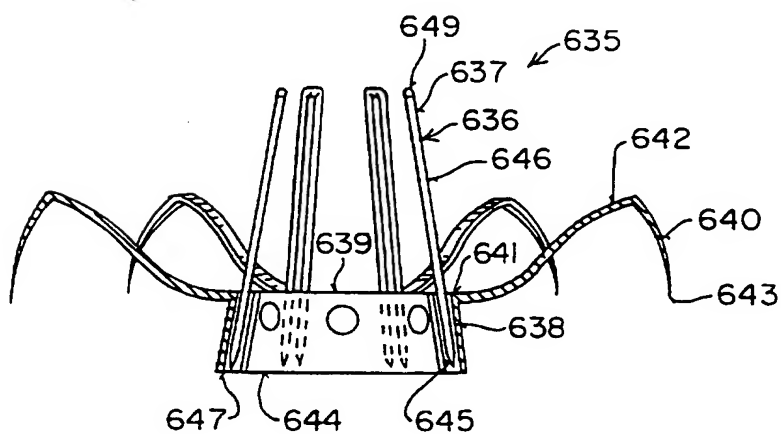


FIG. 47B

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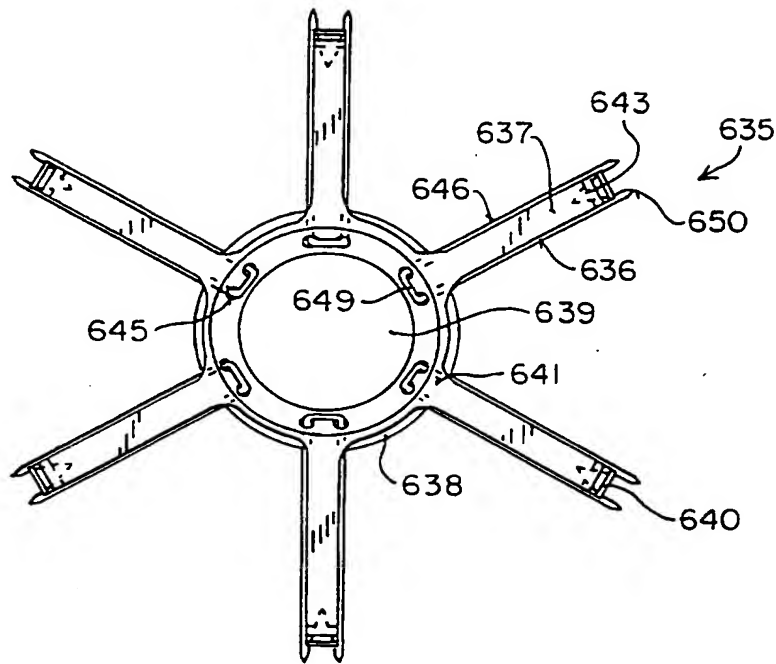


FIG. 48A

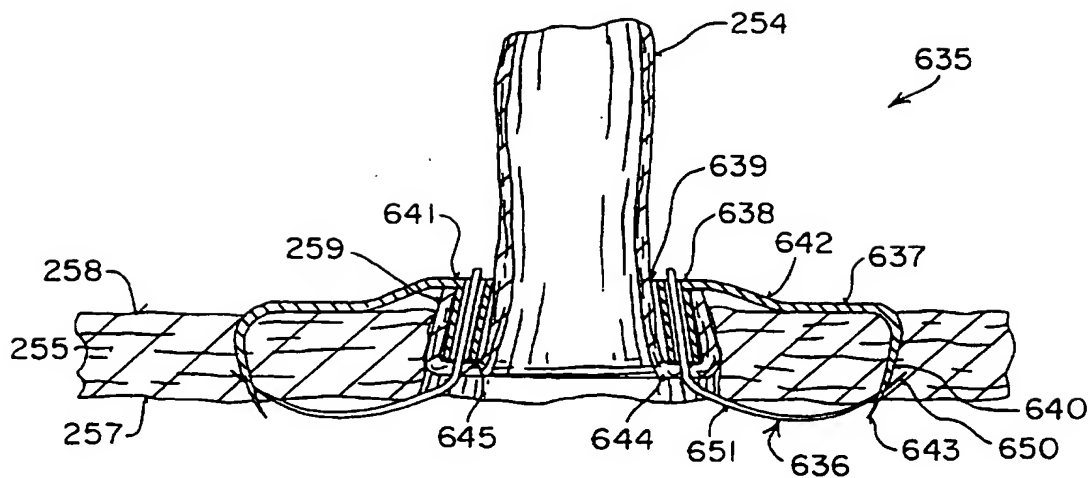


FIG. 48B

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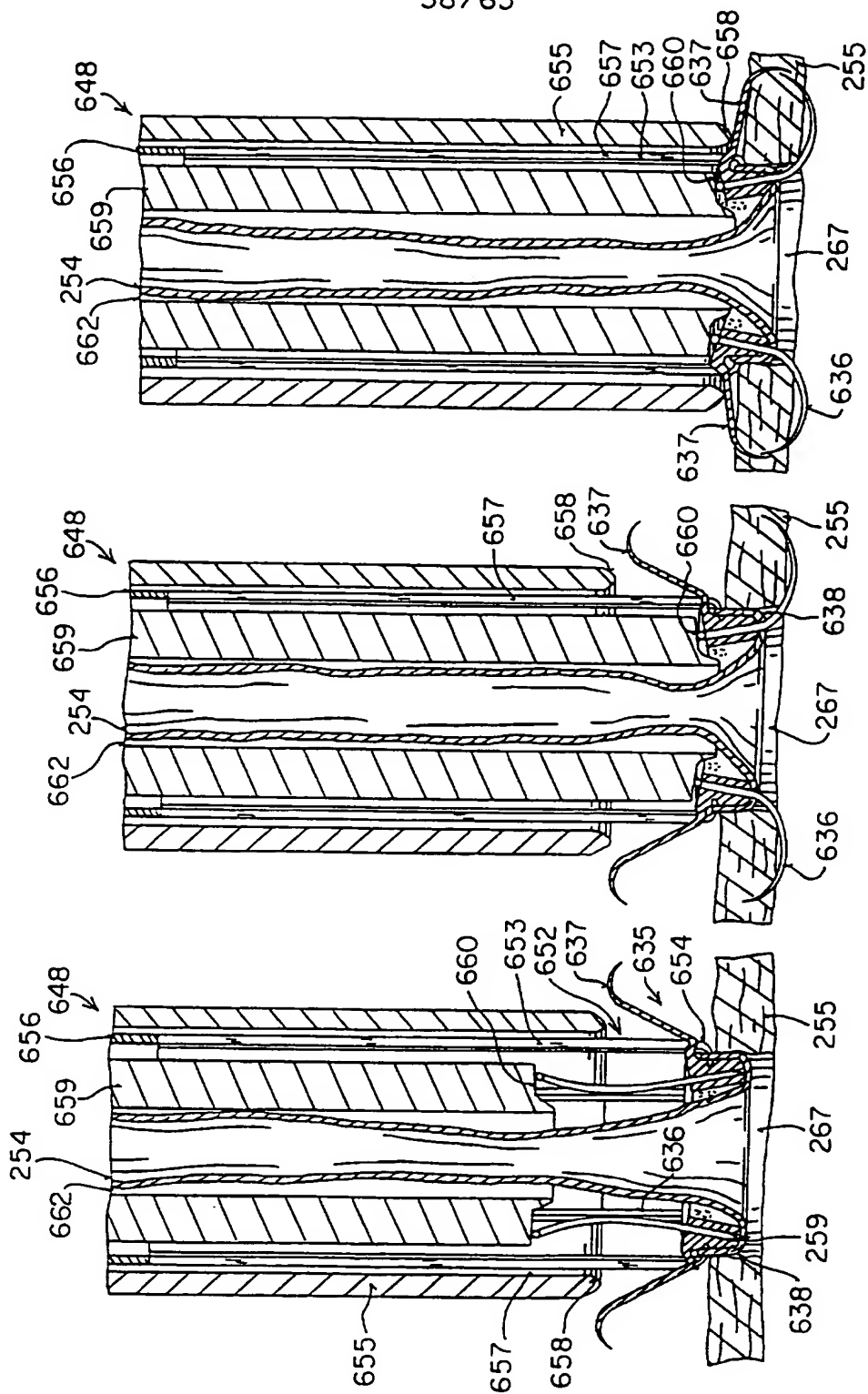
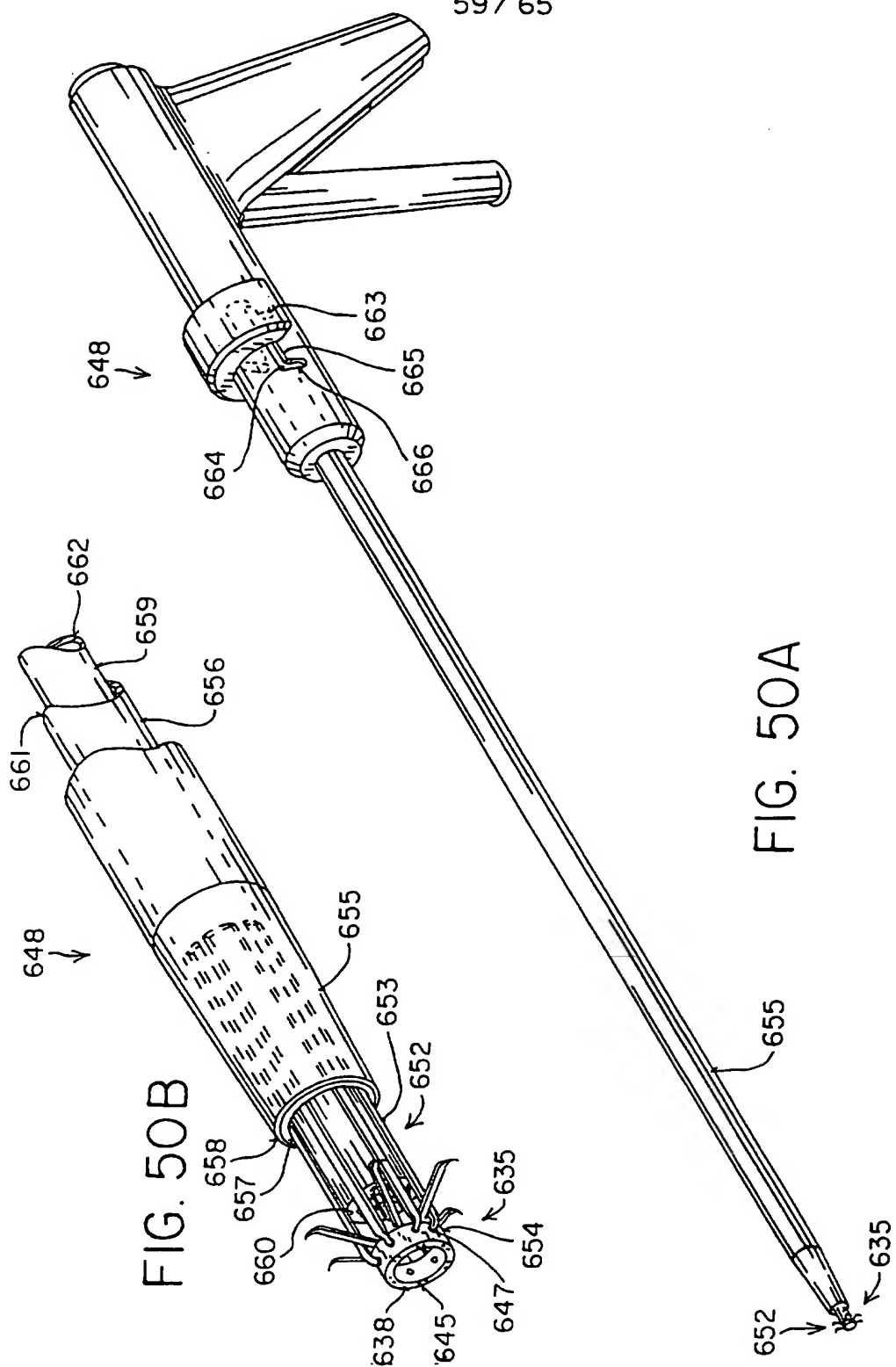


FIG. 49C

FIG. 49B

FIG. 49A



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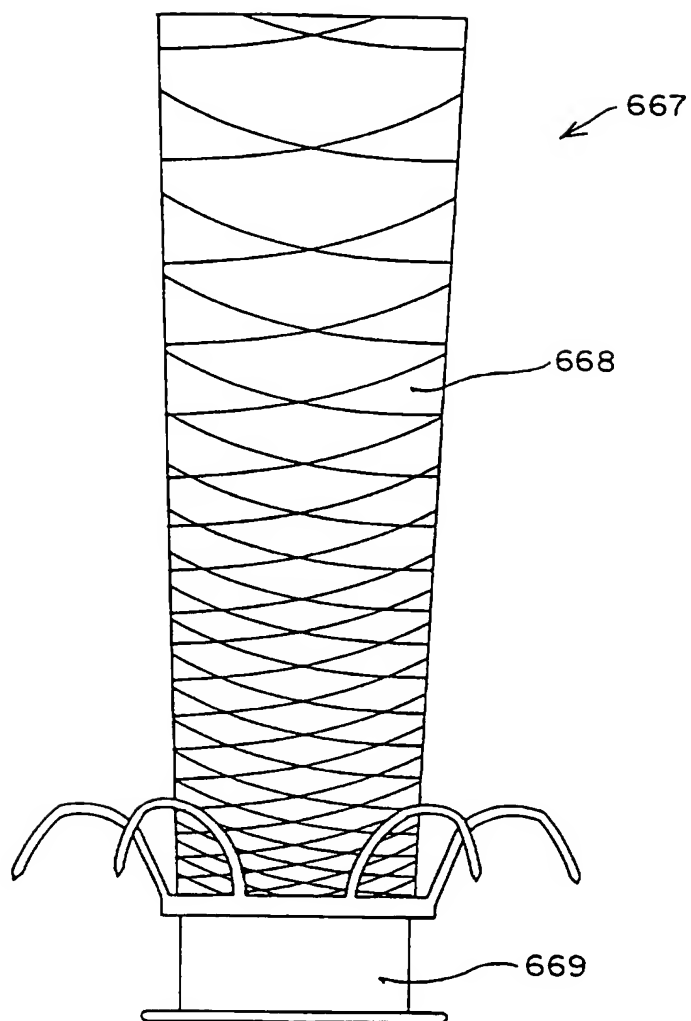


FIG. 51

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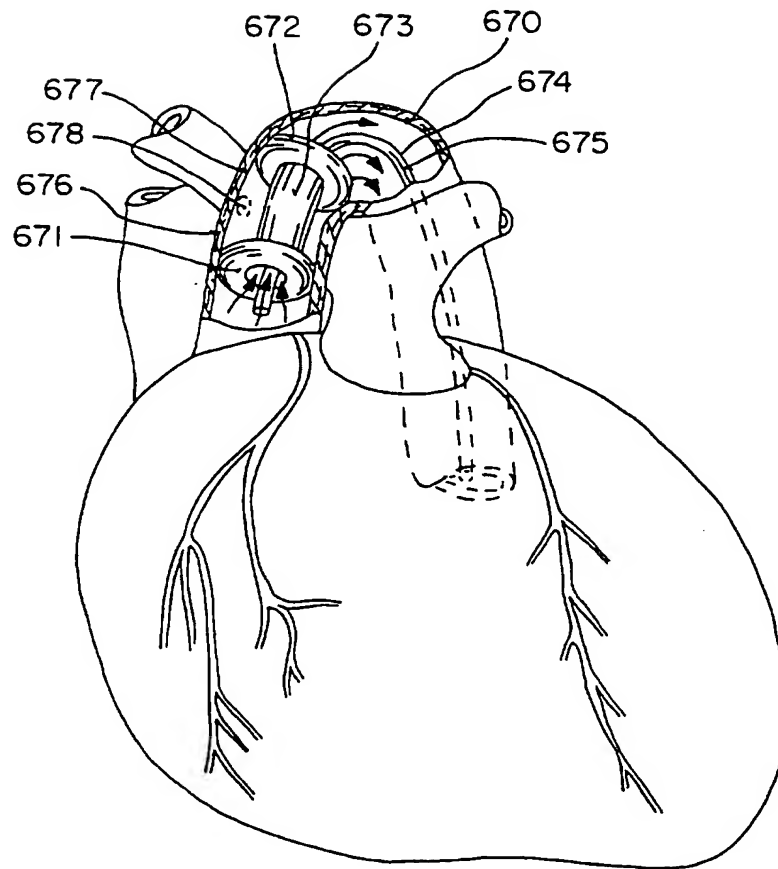


FIG. 52

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FIG. 53

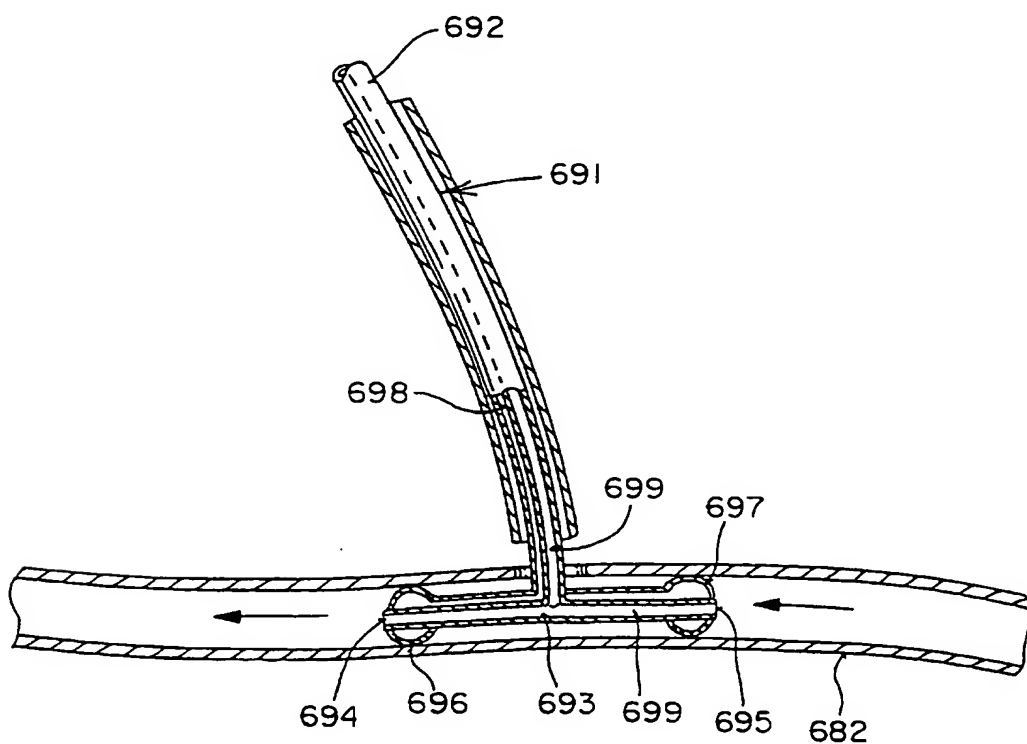
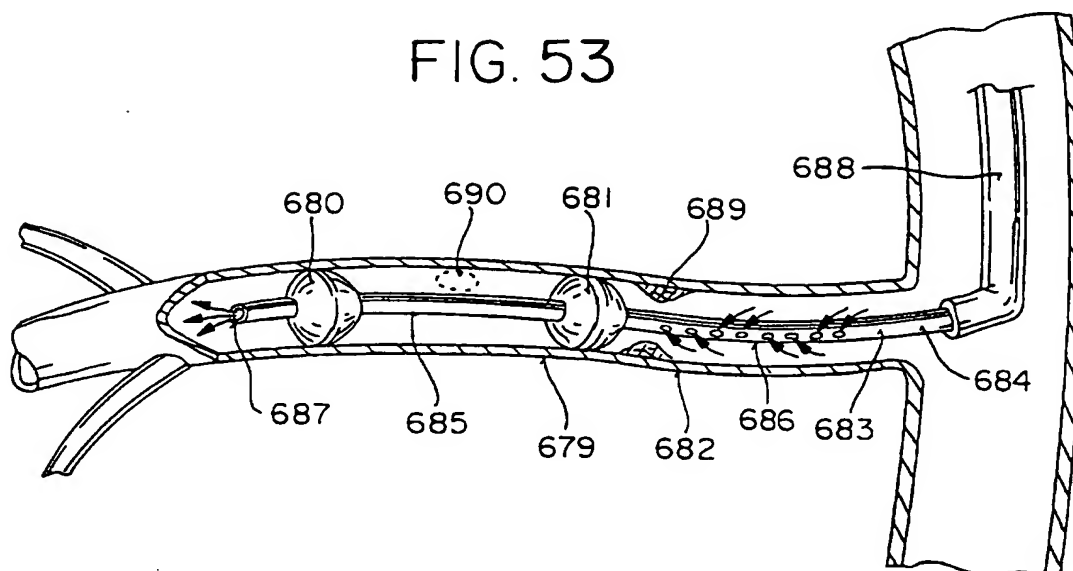


FIG. 54

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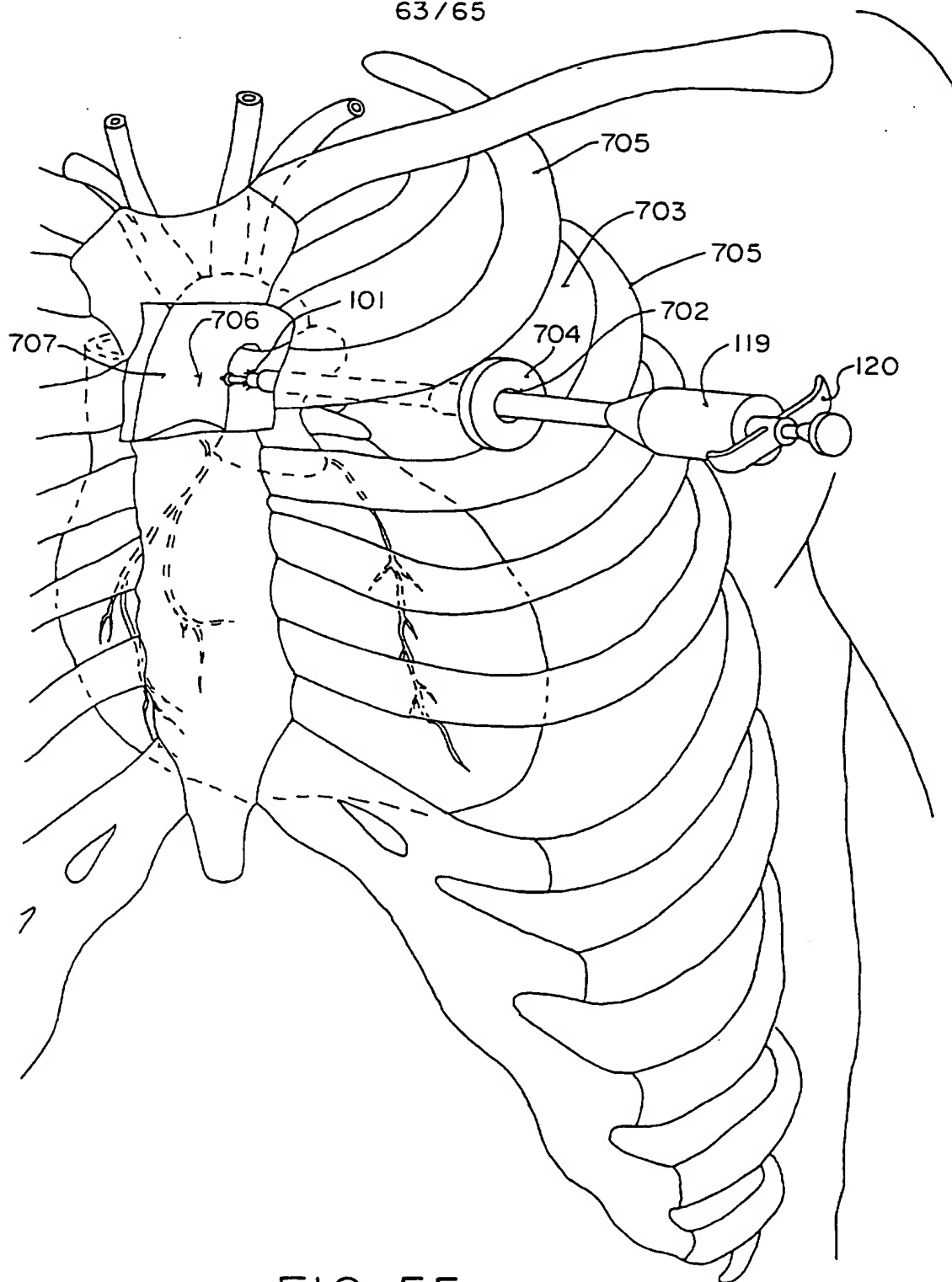


FIG. 55

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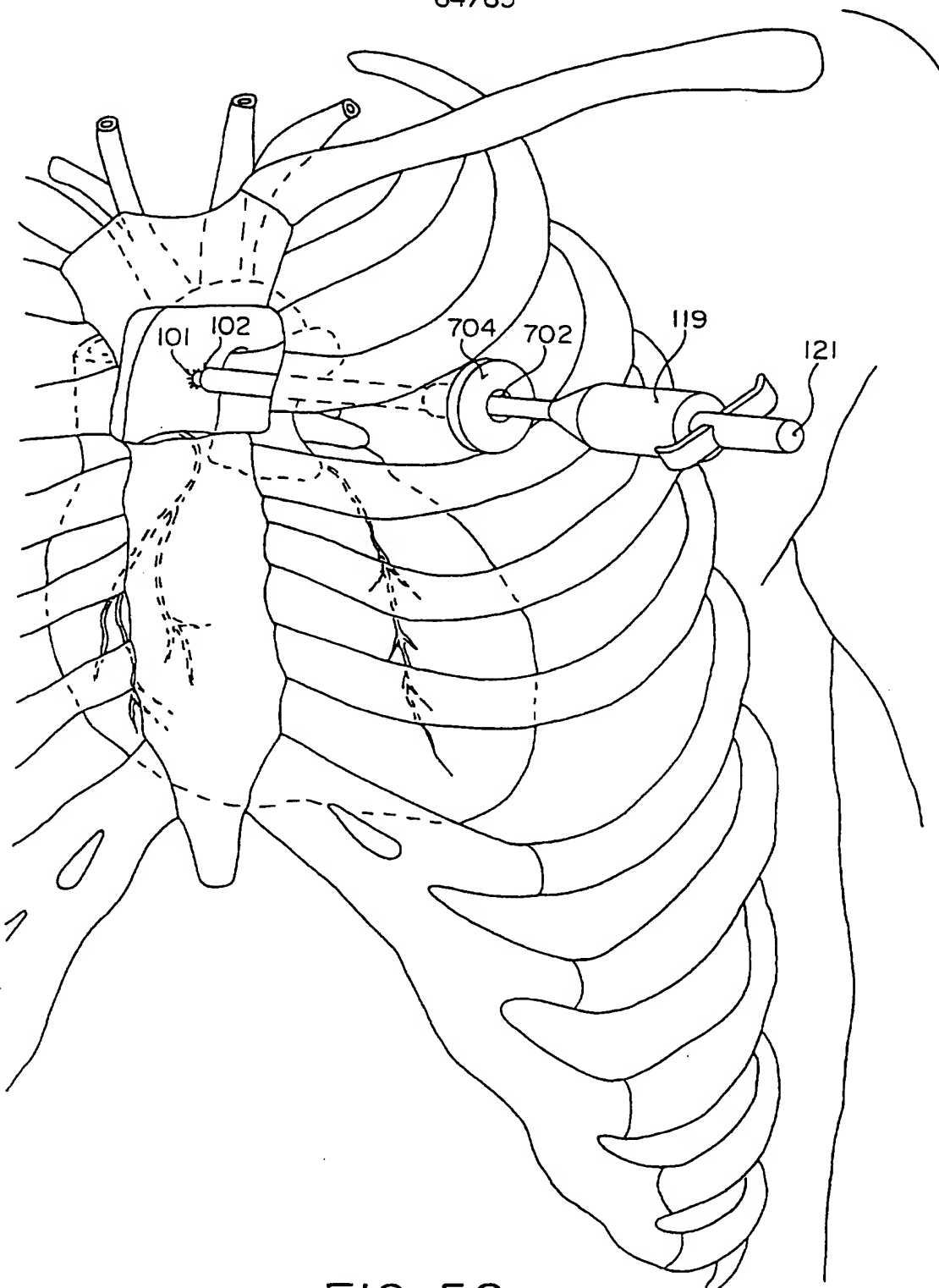


FIG 56  
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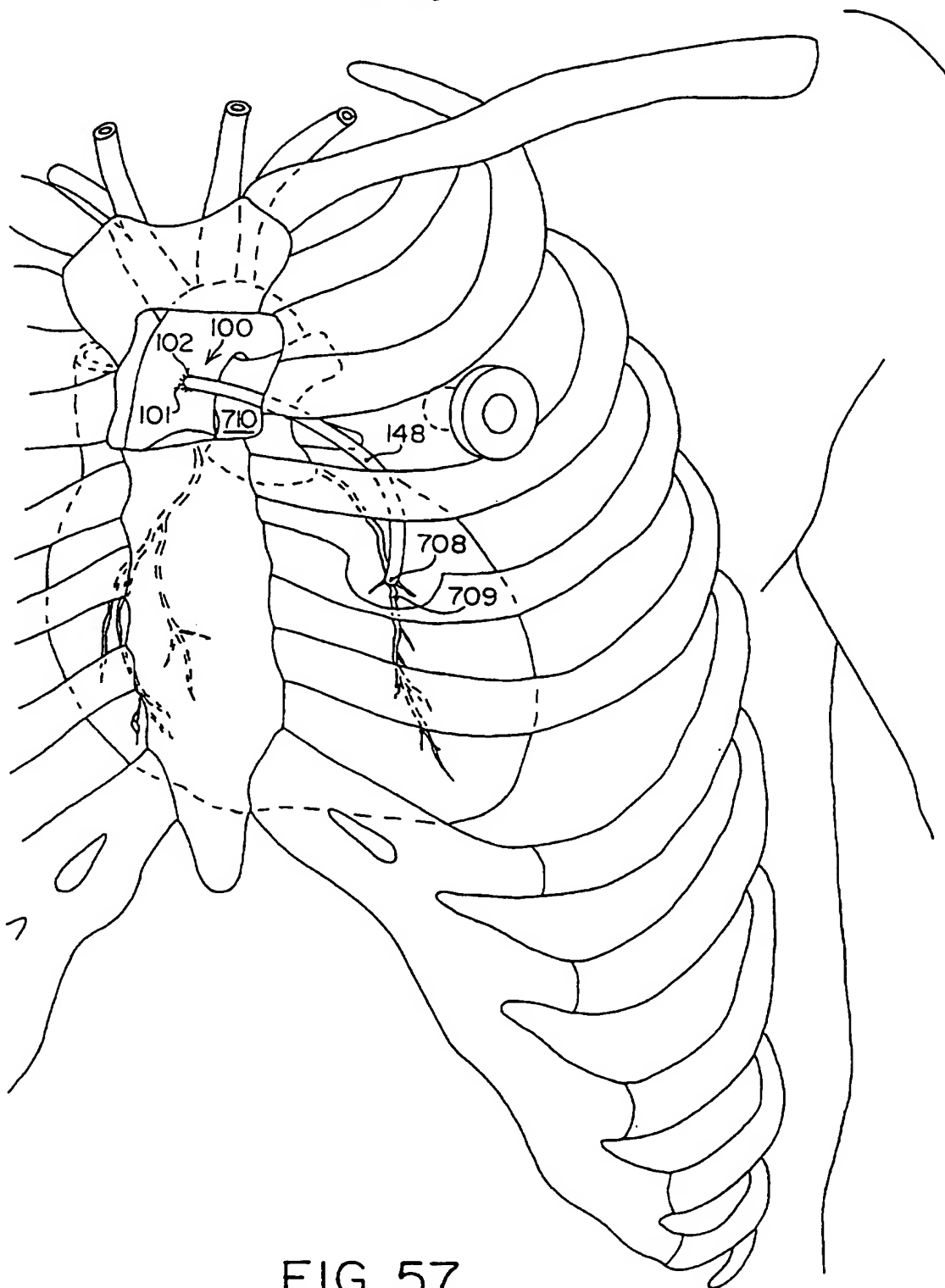


FIG. 57  
SUBSTITUTE SHEET (RULE 26)

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US96/01890

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61B 17/04

US CL : 606/153, 219

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/139, 153, 154, 155, 219

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,917,087 (WALSH ET AL) 17 April 1990, see entire document.	1-6, 14, 16, 22-24, 26-28, 36-37, 39-42, 44, 50-53 and 55-56
Y	US, A, 5,234,447 (KASTER ET AL) 10 August 1993, see cols. 1 and 2.	45-49, 57-59 and 64-66
A	US, A, 4,917,091 (BERGGREN ET AL) 17 August 1990, see col. 1, lines 63-68 and col. 2, lines 1-26.	1-66

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A* document defining the general state of the art which is not considered to be part of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*E* earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
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*U* document referring to an oral disclosure, use, exhibition or other means	
*P* document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

09 JUNE 1996

Date of mailing of the international search report

03 JUL 1996

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

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GARY JACKSON

Telephone No. (703) 305-3590

PCT

ВСЕМИРНАЯ ОРГАНИЗАЦИЯ  
ИНТЕЛЛЕКТУАЛЬНОЙ СОБСТВЕННОСТИ  
Международное бюро

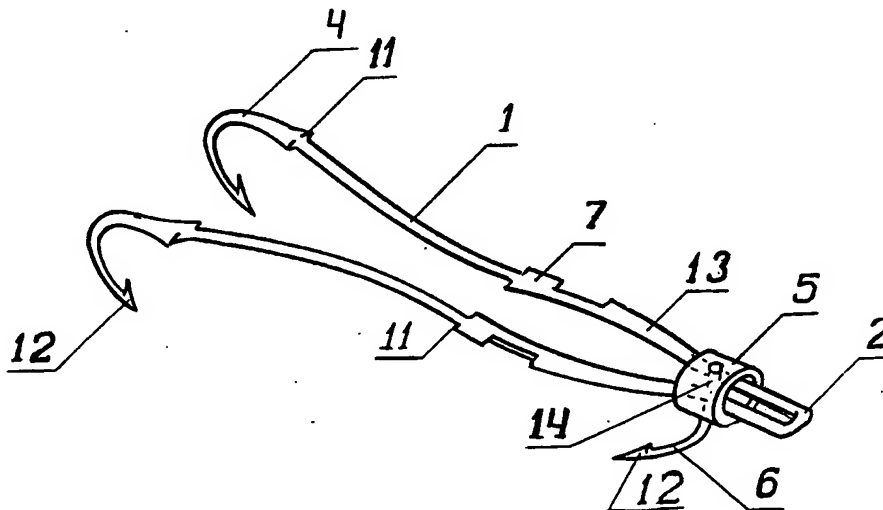


МЕЖДУНАРОДНАЯ ЗАЯВКА, ОПУБЛИКОВАННАЯ В СООТВЕТСТВИИ  
С ДОГОВОРом О ПАТЕНТНОЙ КООПЕРАЦИИ (РСТ)

(51) Международная классификация изобретения: A61F 2/06	A1	(11) Номер международной публикации: WO 95/26170 (43) Дата международной публикации: 5 октября 1995 (05.10.95)
(21) Номер международной заявки: PCT/RU95/00056 (22) Дата международной подачи: 27 марта 1995 (27.03.95) (30) Данные о приоритете: 94010685 28 марта 1994 (28.03.94) RU (71)(72) Заявители и изобретатели: КРУЧИНИН Борис Петрович [RU/RU]; 121609 Москва, Рублёвское шоссе, д. 28, корп. 3, кв. 208 (RU) [KRUCHININ, Boris Petrovich, Moscow (RU)]. КАРПЕНКО Владимир Леонидович [RU/RU]; 113186 Москва, ул. Нагорная, д. 29, корп. 2, кв. 67 (RU) [KARPENKO, Vladimir Leonidovich, Moscow (RU)].		(81) Указанные государства: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, US, UZ, VN, европейский патент (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), патент OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), патент ARIPO (KE, MW, SD, SZ, UG).  Опубликована С отчетом о международном поиске.

(54) Title: MICROSURGICAL CLAMP

(54) Название изобретения: МИКРОХИРУРГИЧЕСКИЙ ФИКСАТОР



(57) Abstract

The invention relates to medicine and can be used as a tissue clamp or fixing element for prostheses. The proposed microsurgical clamp consists of a flexible curved shaft with a back edge (2) and two limbs (1) or blades provided with end hooks (4). The clamp has a sleeve (5) which can slide and lock on the shaft or blade. The sleeve is provided with at least one hook (6) which opposes the end hooks. The back edge, sections of the blades contiguous with it or the end of the blade facing the end hooks are designed as the actuating elements of the adjusting device.

Изобретение относится к области медицины и может использоваться как фиксатор тканей или фиксирующий элемент протезов.

Микрохирургический фиксатор состоит из упругого изогнутого стержня со спинкой 2 и двумя ножками 1 или пластины, снабженных концевыми крючками 4. Фиксатор содержит втулку 5, установленную с возможностью перемещения и фиксации на стержне или пластине. Втулка снабжена по крайней мере одним крючком 6, ориентированным навстречу концевым крючкам. Спинка, примыкающие к ней участки ножек, либо конец пластины, противоположный концевым крючкам, выполнены под исполнительные элементы установочного средства.

#### ИСКЛЮЧИТЕЛЬНО ДЛЯ ЦЕЛЕЙ ИНФОРМАЦИИ

Коды, используемые для обозначения стран-членов РСТ на титульных листах брошюр, в которых публикуются международные заявки в соответствии с РСТ.

AT	Австрия	FI	Финляндия	MR	Мавритания
AU	Австралия	FR	Франция	MW	Малави
BB	Барбадос	GA	Габон	NE	Нигер
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BF	Буркина Фасо	GN	Гвинея	NO	Норвегия
BG	Болгария	GR	Греция	NZ	Новая Зеландия
BJ	Бенин	HU	Венгрия	PL	Польша
BR	Бразилия	IE	Ирландия	PT	Португалия
CA	Канада	IT	Италия	RO	Румыния
CF	Центральноафриканская Республика	JP	Япония	RU	Российская Федерация
BY	Беларусь	KP	Корейская Народно-Демократическая Республика	SD	Судан
CG	Конго	KR	Корейская Республика	SE	Швеция
CH	Швейцария	KZ	Казахстан	SI	Словения
CI	Кот д'Ивуар	LI	Лихтенштейн	SK	Словакия
CM	Камерун	LK	Шри Ланка	SN	Сенегал
CN	Китай	LU	Люксембург	TD	Чад
CS	Чехословакия	LV	Латвия	TG	Того
CZ	Чешская Республика	MC	Монако	UA	Украина
DE	Германия	MG	Малагаскар	US	Соединенные Штаты Америки
DK	Дания	ML	Мали	UZ	Узбекистан
ES	Испания	MN	Монголия	VN	Вьетнам

## МИКРОХИРУРГИЧЕСКИЙ ФИКСАТОР

Область техники

Изобретение относится к медицине, а именно к хирургии, и может использоваться как фиксатор тканей или фиксирующий элемент протезов.

Предшествующий уровень техники

Известен зажим (заявка Японии N63-6016, кл. A61B 17/22), содержащий основание, бранши, захваты, и известно устройство для его установки, состоящее из вставленных друг в друга двух трубок, тросика с крючком, а также съемного кольца на торце внутренней трубки, которое надвигается на бранши зажима и закрывает захваты. Недостатком данной конструкции является то, что конструкция известного зажима не позволяет использовать его для фиксации протеза.

15 Известно фиксирующее приспособление (патент США N4683895, кл. A61B 17/04), содержащее полукруглые элементы с трудносгибаемым участком соединения, продолжающиеся в скобы со встречно направленными крючками. При сгибании фиксатора в месте соединения его переводят из открытого положения в за-  
20 жимающее, при котором он закрепляет на себе трубчатый протез и фиксируется к тканям крючками. Недостатком известного фиксатора является то, что его размеры определяются величиной прикрепляемого протеза, а также то, что он лишь удерживает на себе протез и не соприкасает его с тканями, что не-

обходимо для процессов вживления.

### Раскрытие изобретения

Технической задачей изобретения является создание более совершенного устройства, позволяющего фиксировать ткань и  
05 протез в ткани.

Указанная задача в первом варианте предложенного микрохирургического фиксатора, содержащего упругий изогнутый стержень со спинкой и двумя ножками, имеющими концевые крючки, решается тем, что он содержит втулку, установленную с  
10 возможностью перемещения вдоль внешних поверхностей ножек от исходного положения до положения фиксации, при этом втулка снабжена по меньшей мере одним дополнительным крючком, ориентированным навстречу концевым крючкам, а спинка и примыкающие к ней участки ножек выполнены под исполнительные эле-  
15 менты установочного средства.

Указанная задача решается также тем, что для предотвращения поворотов втулки вокруг оси, она снабжена штифтом, расположенным между ножками, либо тем, что втулка дополнительно содержит упругую пластину в виде защелки, либо эту  
20 функцию выполняет часть дополнительного крючка, выполненного в виде упругой изогнутой пластины, размещенная внутри втулки.

Кроме того, для решения указанной задачи, с целью фиксации втулки, на ножках выполнены втулочные стопорные уступы,  
25 причем втулочные стопорные уступы выполняются как изгибы стержня, выступы или выемки, а втулка может дополнительно фиксироваться при помощи защелки, как выполненной из отдельной пластины, так и являющейся частью дополнительного крючка.

Кроме того, для решения указанной задачи, с целью удерживания втулки в исходной позиции, стержень изогнут симметрично и имеет прогибы ножек в противоположные стороны на участках от спинки до стопорных уступов, достижению этой же  
30 цели служит взаимодействие стопорных уступов и втулочной за-  
35 щелки.

Для надежности фиксации протеза, на участках ножек между концевыми крючками и втулочными стопорными уступами выполне-

ны фиксирующие бородки, а для надежности крепления фиксатора в тканях на концевых и дополнительных крючках имеются фиксирующие выступы.

С целью наиболее оптимального соприкосновения концевых  
05 крючков с тканями, предусматривается их изгиб к ножкам под углом  $90-179^\circ$ , а также их разворот относительно плоскости симметрии фиксатора на угол  $10-35^\circ$ , при этом аналогичный разворот предусмотрен для крайних дополнительных крючков втулки. Эту же цель преследует выполнение перехода ножек в  
10 концевые крючки с пружинными полувитками или по меньшей мере одним пружинным витком, что в свою очередь придает крючку упругие свойства.

Указанная задача решается тем, что для наиболее благоприятного соприкосновения протеза и тканей, ножки выполняются  
15 дугообразными или с изгибом в сторону концевых крючков под углом  $1-90^\circ$  на участках ножек от стопорных изгибов до крючков.

Для повышения жесткости конструкции фиксатора, на участках стопорных уступов предусматривается соединение ножек  
20 между собой.

Кроме того, форма и площадь поперечного сечения на различных участках упругого стержня различны, причем форма и площадь поперечного сечения на симметричных участках ножек одинакова.

25 Указанная задача решается также тем, что для взаимодействия фиксатора с установочным устройством спинка выполнена с дополнительным выступом.

Во втором варианте предлагаемого микрохирургического фиксатора, содержащего упругий стержень, изогнутый на одном  
30 конце с образованием концевого крючка и имеющего другой крючок, ориентированный навстречу концевому, указанная задача решается тем, что стержень выполнен в виде пластины и дополнительно снабжен втулкой, установленной с возможностью перемещения вдоль пластины от исходного положения до положения  
35 фиксации, при этом крючок, ориентированный навстречу концевому, соединен со втулкой, а часть пластины, противоположная концевому крючку, выполнена под исполнительные элементы установочного средства.

Указанная задача решается также тем, что для предотвра-

щения поворотов втулки вокруг оси, она дополнительно содержит упругую пластину в виде защелки, либо эту функцию выполняет часть дополнительного крючка, выполненного в виде упругой изогнутой пластины, размещенная внутри втулки.

- 05      Указанная задача решается также тем, что фиксатор дополнительно снабжен одним или более крючками, образованными рядом с концевым крючком путем выполнения по меньшей мере одного выреза на пластине, либо присоединенными к пластине.

- 10      Кроме того, для решения указанной задачи, с целью фиксации втулки, на пластине предусмотрен по меньшей мере один втулочный стопорный уступ, выполненный в виде изгибов пластины, выступов или выемок, а втулка может дополнительно фиксироваться при помощи защелки, как выполненной из отдельной пластины, так и являющейся частью дополнительного крючка.

15      Кроме того, для решения указанной задачи, с целью удерживания втулки в исходной позиции, стопорные уступы в виде изгибов пластины находятся во взаимодействии со втулочной защелкой.

- 20      Кроме того, для фиксации втулки на ней предусмотрен стопорный крючок, установленный с возможностью зацепления с вырезом пластины или с дужкой, размещенной на пластине.

25      Для надежности фиксации протеза, на участках ножек между концевыми крючками и втулочными стопорными уступами выполнены фиксирующие бороздки, а для надежности крепления фиксатора в тканях на концевых и крючках, соединенных со втулкой, имеются фиксирующие выступы.

- 30      С целью наиболее оптимального соприкосновения концевых крючков с тканями, предусматривается их изгиб к пластине под углом  $90-179^\circ$ , а также их разворот относительно плоскости симметрии фиксатора на угол  $10-35^\circ$ , при этом аналогичный разворот предусмотрен для крайних дополнительных крючков втулки. Эту же цель преследует выполнение перехода ножек в концевые крючки с пружинными полувитками, что в свою очередь
- 35      придает крючку упругие свойства.

Указанная задача решается тем, что для наиболее благоприятного соприкосновения протеза и тканей, пластина выполняется дугообразной или с изгибом в сторону концевых крючков под углом  $1-90^\circ$  на участках ножек от стопорных уступов до

концевых крючков.

Указанная задача решается также тем, что часть пластины, противоположная концевому крючку, выполняется с отверстием или выступом для взаимодействия фиксатора с установочным устройством, а также тем, что втулка может быть снабжена более, чем одним крючком.

#### Краткое описание чертежей

Сущность изобретения поясняется чертежами 1-15, где на фиг. 1 и 2 изображен фиксатор по первому варианту выполнения, на фиг. 3 и 4 - фиксатор, закрепленный на установочном средстве, на фиг. 5 - 10 - варианты крепления фиксатора и протеза в ткани, на фиг. 11 и 12 - фиксатор по второму варианту выполнения, на фиг. 13 - фиксатор, закрепленный на установочном средстве, на фиг. 14 и 15 - фрагменты фиксатора с вариантами выполнения узлов фиксации втулки.

#### Варианты осуществления изобретения

Микрохирургический фиксатор содержит упругий изогнутый стержень с ножками 1 и спинкой 2 (первый вариант выполнения) или пластину 3 (второй вариант), а также концевые крючки 4, выполненные на ножках или пластине. На стержне или пластине установлена с возможностью перемещения и фиксации втулка 5, снабженная одним или несколькими крючками 6.

Фиксация втулки на стержне или пластине осуществляется с использованием втулочных стопорных уступов 7, которые могут быть выполнены в виде выступов (фиг. 1), выемок или изгибов ножек стержня или пластины (фиг. 2, 11, 12), а также фиксация втулки может осуществляться путем зацепления стопорного крючка 8 за вырез пластины 9 или дужку 10, выполненную на пластине (фиг. 14, 15), либо с использованием пружинной защелки (фиг. 2, 11, 12).

Для фиксации протеза на стержне или пластине выполнены фиксирующие бородки 11, на крючках выполнены фиксирующие выступы 12. На ножках стержня могут быть выполнены изгибы 13 (фиг. 1). Для предотвращения поворотов втулка снабжена либо штифтом 14, либо упругой пластиной 15, которая может быть

как отдельным элементом, так и частью крючка 6.

Стопорный крючок 8 и крючок 6 могут быть изготовлены из одной пластины, как показано на фиг. 14 и 15, а пластина 15 может являться частью крючка 6, как показано на фиг. 2, 11, 12, 05 либо самостоятельным элементом, закрепленным на втулке 5 независимо от крючка 6.

Стержень или пластина могут иметь как дугообразную форму (фиг. 10), так и быть выполнены с изгибом 17 (фиг. 6, 7).

Соединение крючков 4 со стержнем может выполняться с образованием пружинного витка 18 (фиг. 8). Соединение в виде полу- 10 витка 19 может быть выполнено как на стержне, так и на пластине (фиг. 9).

Для работы фиксатора предусмотрено установочное средство (манипулятор). Закрепление фиксатора на нем производится путем совмещения спинки 2 стержня, выступа 20 или отверстия в 15 пластине с торцевым крючком 21 установочного средства. Установочное средство состоит из торцевого крючка 21, выполненного на упругом стержне 22, расположенном внутри трубки 23. Фиксатор работает следующим образом. Протез насаживается на 20 фиксатор, располагаясь на участках ножек стержня или пластины между крючками 4 и стопорными выступами 7, удерживаясь фиксирующими бородавками 11, причем по форме протеза и конфигурации органа выбирается фиксатор с нужным изгибом стержня или пластины и крючков в соответствии с указанными в 25 формуле пределами. Фиксатор неподвижно закрепляется на установочном средстве совмещением спинки 2 стержня, выступа 20 или отверстия с торцевым крючком 21 стержня 22 и введением соединения внутрь трубки 23 на конструктивно определенную величину. При этом торец трубки 23 соприкасается с находя- 30 щейся на исходной позиции втулкой 5.

Для удержания в ней в одном из вариантов выполнения имеются выгнутые в противоположные стороны участки 13 стержня. В другом варианте втулка удерживается на исходной позиции посредством взаимодействия пружинной защелки, выполненной в 35 виде упругой изогнутой пластины 15, со стопорными уступами 7, выполненными в виде изгибов пластины или ножек стержня. Усилием, приложенным к установочному средству, фиксатор прижимается к ткани и крючки 4 вводятся в ее толщу. При поступательном движении трубки 23 относительно неподвижного

05 стержня 22 в сторону фиксатора втулка 5 перемещается по ножкам или пластине до стопорных уступов 7. Втулка фиксируется при взаимодействии со стопорными уступами, либо при взаимодействии пружинной защелки с изгибами ножек стержня или пластины, либо при взаимодействии стопорного крючка с вырезом пластины или дужкой, размещенной на пластине. При фиксации втулки крючками 4 и 6 фиксатор крепится на ткани. Трубка 23 сдвигается с фиксатора до момента разъединения его с манипулятором.

10

### Промышленная применимость

В зависимости от цели использования фиксатора, могут применяться устройства, содержащие один или несколько манипуляторов. В частности, фиксаторы могут применяться в качестве фиксирующих элементов внутрисердечных и внутрисосудистых протезов. При этом, прикрепляясь к тканям, фиксаторы соприкасают и прижимают к ним протез, удерживая его, а большая часть конструкции фиксатора оказывается укрытой в тканях протеза и органа, что способствует процессам вживления и уменьшает опасность тромбообразования. Использование изобретения позволит снизить травматичность оперативных вмешательств.

## ФОРМУЛА ИЗОБРЕТЕНИЯ

1. Микрохирургический фиксатор, содержащий упругий изогнутый стержень со спинкой и двумя ножками, имеющими концевые крючки, отличающийся тем, что содержит втулку, установленную  
05 с возможностью перемещения вдоль внешних поверхностей ножек от исходного положения до положения фиксации, при этом втулка снабжена по меньшей мере одним дополнительным крючком, ориентированным навстречу концевым крючкам, а спинка и при-  
10 мыкающие к ней участки ножек выполнены под исполнительные элементы установочного средства.

2. Фиксатор по п. 1, отличающийся тем, что втулка снабжена штифтом, расположенным между ножками.

3. Фиксатор по п. 1, отличающийся тем, что на ножках выполнен по меньшей мере один втулочный стопорный уступ.

15 4. Фиксатор по п. 3, отличающийся тем, что стержень изогнут симметрично и имеет прогибы ножек в противоположные стороны на участках от спинки до стопорных уступов.

5. Фиксатор по п. 3, отличающийся тем, что стопорные уступы выполнены в виде изгибов стержня, выступов или выемок.

20 6. Фиксатор по п. 3, отличающийся тем, что на участках ножек между концевыми крючками и втулочными стопорными уступами выполнены фиксирующие бороздки.

7. Фиксатор по п. 3, отличающийся тем, что ножки выполнены с изгибом в сторону концевых крючков под углом  $1-90^\circ$  на  
25 участках от стопорных уступов до концевых крючков.

8. Фиксатор по п. 3 или 5, отличающийся тем, что дополнительный крючок выполнен в виде упругой изогнутой пластины, часть которой размещена во втулке.

9. Фиксатор по п. 3 или 5, отличающийся тем, что втулка  
30 дополнительно снабжена защелкой в виде упругой изогнутой пластины.

10. Фиксатор по п. 1, отличающийся тем, что концевые и дополнительные крючки снабжены фиксирующими выступами.

11. Фиксатор по п. п. 1, отличающийся тем, что концевые  
35 крючки изогнуты к ножкам под углом  $90-179^\circ$ .

12. Фиксатор по п. 1, отличающийся тем, что концевые крюч-

ки и/или крайние крючки втулки развернуты относительно плоскости симметрии фиксатора на угол 10-35°.

13. Фиксатор по п. 1, отличающийся тем, что переход ножек в концевые крючки выполнен с пружинным полувитком или по меньшей мере одним пружинным витком.

14. Фиксатор по п. 1, отличающийся тем, что ножки выполнены дугообразными.

15. Фиксатор по п. 1, отличающийся тем, что на участке стопорных уступов ножки соединены между собой.

16. Фиксатор по п. 1, отличающийся тем, что стержень имеет различную форму и площадь поперечного сечения на различных участках, причем форма и площадь поперечного сечения на симметричных участках ножек одинакова.

17. Микрохирургический фиксатор, содержащий упругий стержень, изогнутый на одном конце с образованием концевого крючка и имеющий другой крючок, ориентированный навстречу концевому, отличающийся тем, что стержень выполнен в виде пластины и дополнительно снабжен втулкой, установленной с возможностью перемещения вдоль пластины от исходного положения до положения фиксации, при этом крючок, ориентированный навстречу концевому, соединен со втулкой, а часть пластины, противоположная концевому крючку, выполнена под исполнительные элементы установочного средства.

18. Фиксатор по п. 17, отличающийся тем, что на пластине выполнен по меньшей мере один втулочный стопорный уступ.

19. Фиксатор по п. 18, отличающийся тем, что стопорные уступы выполнены в виде изгибов пластины, выступов или выемок.

20. Фиксатор по п. 18, отличающийся тем, что на участке пластины между концевым крючком и втулочными стопорными уступами выполнены фиксирующие бородки.

21. Фиксатор по п. 18, отличающийся тем, что пластина выполнена с изгибом в сторону концевого крючка под углом 1-90° на участке от втулочных стопорных уступов до концевого крючка.

22. Фиксатор по п. 18, отличающийся тем, что втулка дополнительно снабжена защелкой в виде упругой изогнутой пластины.

23. Фиксатор по п. 17 или 18, отличающийся тем, что крю-

чок, соединенный со втулкой, выполнен в виде изогнутой пластины, часть которой размещена во втулке.

24. Фиксатор по п. 17, отличающийся тем, что втулка дополнительно снабжена по меньшей мере одним крючком.

05 25. Фиксатор по п. 17, отличающийся тем, что он снабжен одним или более концевыми крючками, присоединенными к пластине.

26. Фиксатор по п. 17, отличающийся тем, что он дополнительно снабжен одним или более крючками, образованными рядом  
10 с концевым крючком путем выполнения по меньшей мере одного выреза на пластине.

27. Фиксатор по п. 26, отличающийся тем, что втулка дополнительно снабжена стопорным крючком, установленным с возможностью зацепления с вырезом пластины.

15 28. Фиксатор по любому из п. 17, 24, 25, 26, отличающийся тем, что концевые крючки и крючки, соединенные со втулкой, снабжены фиксирующими выступами.

29. Фиксатор по любому из п. 24, 25, 26, отличающийся тем, что крайние концевые крючки и/или крайние крючки втулки раз-  
20 вернуты относительно плоскости симметрии пластины на угол 10-35°.

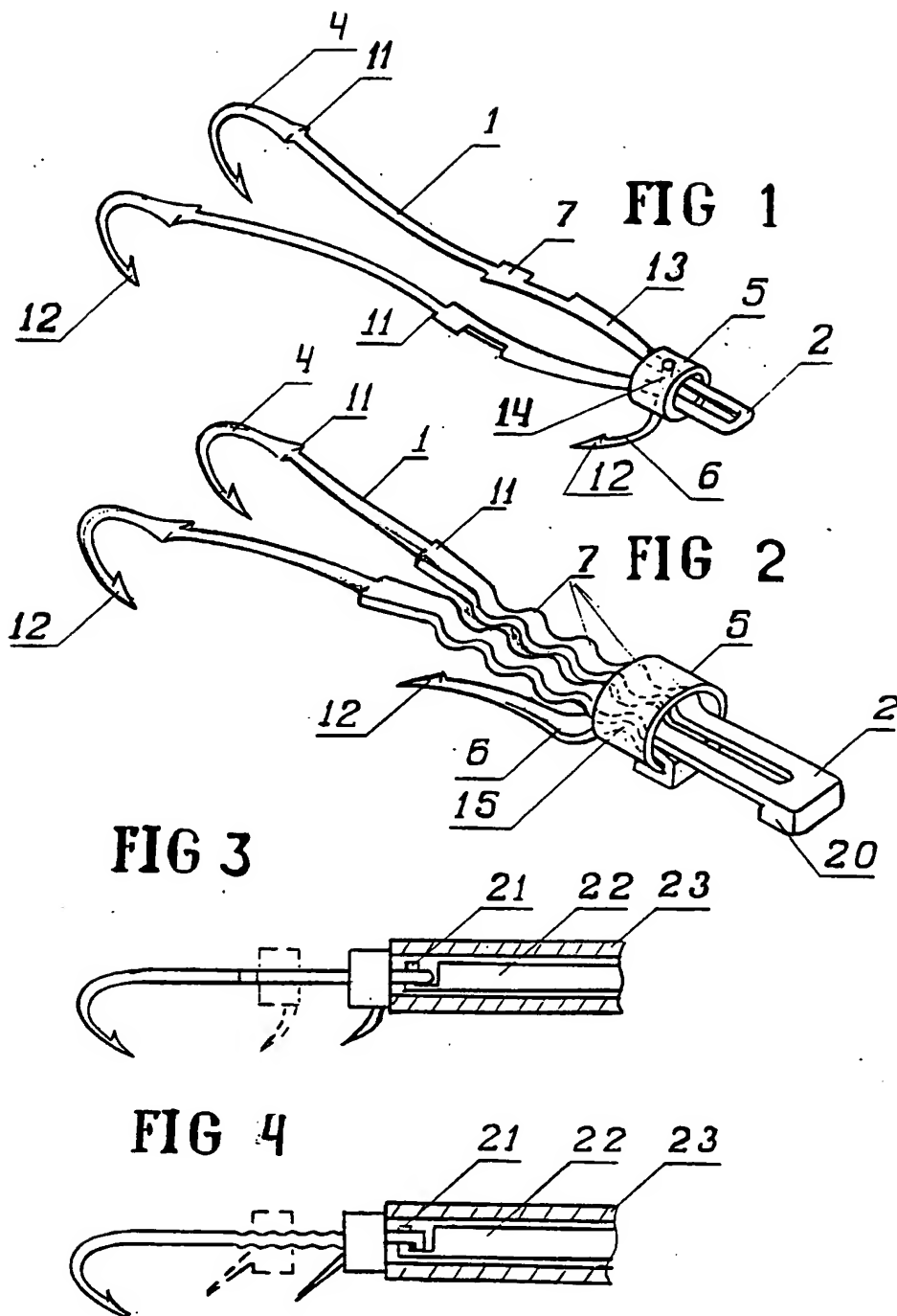
30. Фиксатор по п. 25 или 26, отличающийся тем, что концевые крючки изогнуты к пластине под углом 90-179°.

31. Фиксатор по п. 25 или 26, отличающийся тем, что пере-  
25 ход пластины в концевые крючки выполнен с пружинным полувитком.

32. Фиксатор по п. 17, отличающийся тем, что втулка дополнительно снабжена стопорным крючком, установленным с возможностью зацепления с дужкой, установленной на пластине.

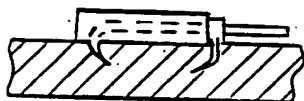
30 33. Фиксатор по п. 17, отличающийся тем, что пластина выполнена дугообразной.

34. Фиксатор по п. 17, отличающийся тем, что часть пластины, противоположная концевому крючку, выполнена с отверстием или выступом под исполнительные элементы установочного  
35 средства.

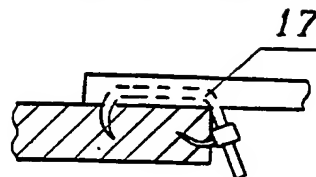


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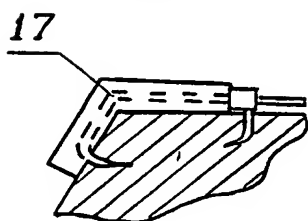
**FIG 5**



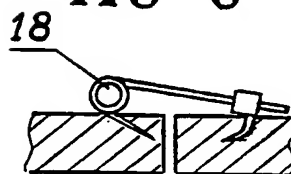
**FIG 6**



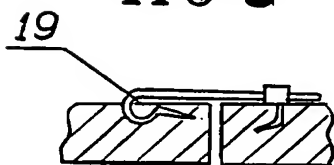
**FIG 7**



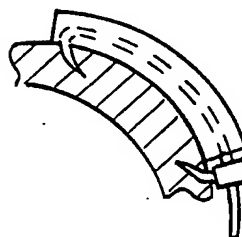
**FIG 8**



**FIG 9**



**FIG 10**



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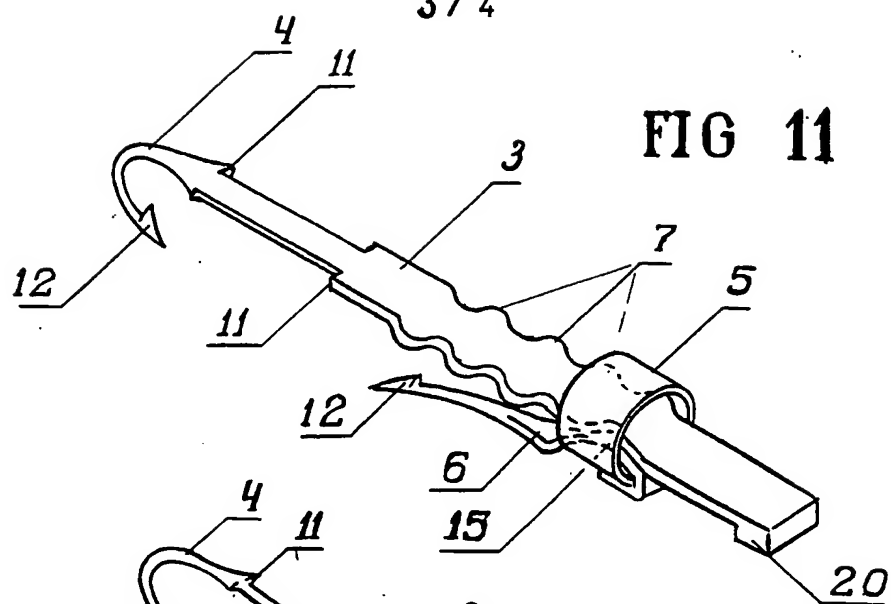


FIG 11

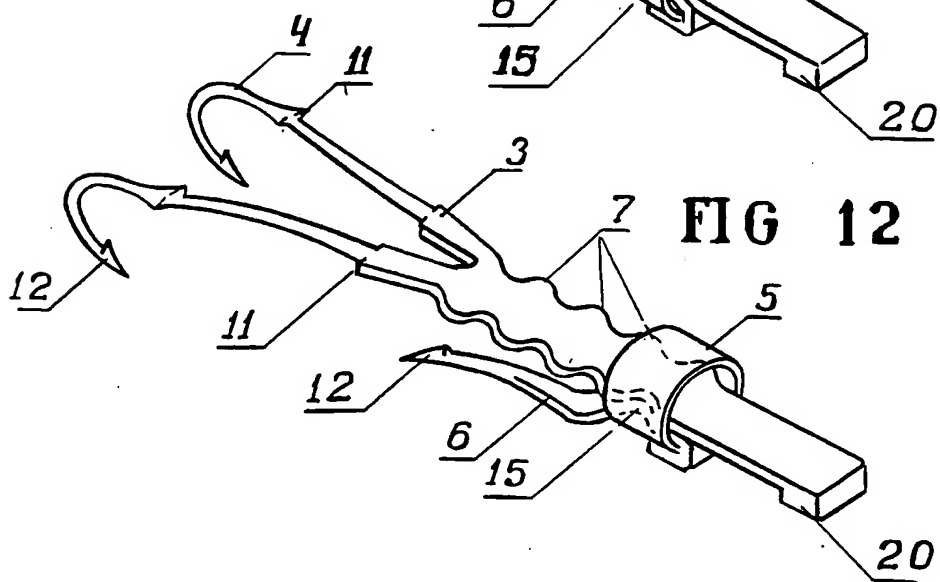
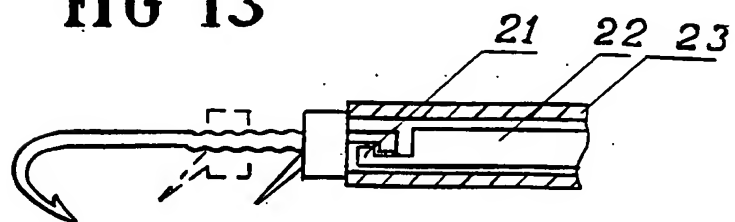


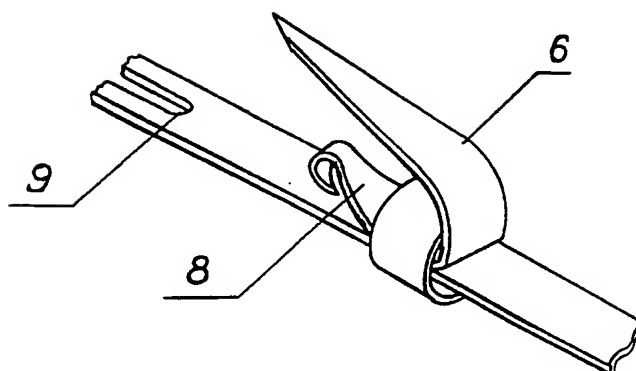
FIG 12

FIG 13

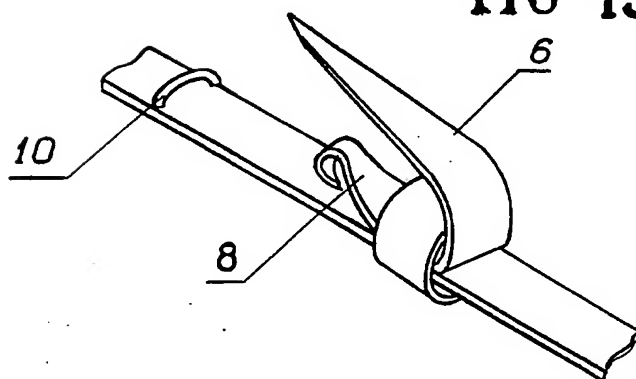


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**FIG 14**



**FIG 15**



## INTERNATIONAL SEARCH REPORT

International application No.

PCT/RU 95/00056

## A. CLASSIFICATION OF SUBJECT MATTER

Int.Cl. 6 A61F 2/06

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Int.Cl. 6 A61F 2/06; A61B 17/02, 17/03, 17/064, 17/068, 17/08  
A61B 17/10, 17/122

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4531522 (Ethicon, Inc.) 30 July 1985 (30.07.85)	1,3,4,5,6,7, 11,14,15,20
A	US, A, 4073298 (New Research & Development Lab., Inc.) 14 February 1978 (14.02.78)	1, 17, 18, 19, 21, 22, 24, 25, 32
A	SU, A, 1161094 (S.A. Popov), 15 June 1985 (15.06.85)	1, 31, 34
A	US, A 2717592 (Medical Specialties, Inc., a corporation of Michigan), 13 September 1955 (13.09.55)	2, 9
A	SU, A, 950356 (Tselinsgradsky gosudarstvenny meditsinsky institut) 15 August 1982 (15.08.82)	8, 23, 26, 33
A	SU, A, 848001 (M.A. Moroz) 23 July 1981 (23.07.81)	9, 27

☒ Further documents are listed in the continuation of Box C.☐ See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&amp;" document member of the same patent family

Date of the actual completion of the international search

24 April 1995 (24.04.95)

Date of mailing of the international search report

18 May 1995 (18.05.95)

Name and mailing address of the ISA/ RU

Authorized officer

Facsimile No.

Telephone No.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/RU 95/00056

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	SU, A, 244558 (Astrakhansky gosudarstvennyy meditsinsky institut imeni A.V. Lunacharskogo) 8 October 1969 (08.10.69)	10, 12, 13, 28, 29, 30
A	US, A, 4534352 (United States Surgical Corporation), 13 August 1985 (13.08.85)	16

# ОТЧЕТ О МЕЖДУНАРОДНОМ ПОИСКЕ

Международная заявка No  
PCT/RU 95/00056

<p>А. КЛАССИФИКАЦИЯ ПРЕДМЕТА ИЗОБРЕТЕНИЯ: A61F 2/06 Согласно Международной патентной классификации (МКИ-6)</p>		
<p>В. ОБЛАСТИ ПОИСКА:</p>		
<p>Проверенный минимум документации (Система классификации и индексы) МКИ-6: A61F 2/06; A61B 17/02, 17/03, 17/064, 17/068, 17/08 A61B 17/10, 17/122</p>		
<p>Другая проверенная документация в той мере, в какой она включена в поисковые подборки:</p>		
<p>Электронная база данных, использовавшаяся при поиске (название базы и, если возможно, поисковые термины):</p>		
<p>С. ДОКУМЕНТЫ, СЧИТАЮЩИЕСЯ РЕЛЕВАНТНЫМИ</p>		
Категория *)	Ссылки на документы с указанием, где это возможно, релевантных частей	Относится к пункту No.
A	US, A. 4531522 (Ethicon, Inc.), 30 июля 1985 (30.07.85)	1,3,4,5,6,7 11,14,15,20
A	US, A. 4073298 (New Research & Development Lab., Inc.), 14 февраля 1978 (14.02.78)	1,17,18,19 21,22,24, 25,32
<p><input checked="" type="checkbox"/> последующие документы указаны в продолжении графы С <input type="checkbox"/> данные о патентах-аналогах указаны в приложении</p>		
<p>* Особые категории ссылок документов:          "А" - документ, определяющий общий уровень техники.          "Е" - более ранний документ, но опубликованный на дату международной подачи или после нее.          "О" - документ, относящийся к устному раскрытию, экспонированию и т.д.          "Р" - документ, опубликованный до даты международной подачи, но после даты испрашиваемого приоритета.          "Т" - более поздний документ, опубликованный после даты приоритета и приведенный для понимания изобретения.          "Х" - документ, имеющий наиболее близкое отношение к предмету поиска, порочащий новизну и изобретательский уровень.          "У" - документ, порочащий изобретательский уровень в сочетании с одним или несколькими документами той же категории.          "&amp;" - документ, являющийся патентом-аналогом.</p>		
<p>Дата действительного завершения международного поиска 24 апреля 1995 (24.04.95)</p>		<p>Дата отправки настоящего отчета о международном поиске 13 мая 1995 (13.05.95)</p>
<p>Наименование и адрес Международного поискового органа: Всероссийский научно-исследовательский институт государственной патентной экспертизы, Россия, 121858, Москва, Бережковская наб. 30-1 факс (095)243-33-37, телетайп 114818 ПОДАЧА</p>		<p>Уполномоченное лицо:  А.Ханюкин тел. (095)240-58-88</p>

## ОТЧЕТ О МЕЖДУНАРОДНОМ ПОИСКЕ

Международная заявка No.

PCT/RU 95/00056

С. (Продолжение) ДОКУМЕНТЫ, СЧИТАЮЩИЕСЯ РЕЛЕВАНТНЫМИ		
Категория *)	Ссылки на документы с указанием, где это возможно, релевантных частей	Относится к пункту No.
A	SU. A. 1161094 (С.А.Попов). 15 июня 1985 (15.06.85)	1,31,34
A	US. A. 2717592 (Medical Specialties, Inc. a corporation of Michigan). 13 сентября 1955 (13.09.55)	2,9
A	SU. A. 950356 (Целиноградский государственный медицинский институт), 15 августа 1982 (15.08.82)	8,23,26,33
A	SU. A. 848001 (М.А.Мороз). 23 июля 1981 (23.07.81)	9,27
A	SU. A. 244558 (Астраханский государственный медицинский институт имени А.В.Луначарского), 8 октября 1969 (08.10.69)	10,12,13, 28,29,30
A	US. A. 4534352 (United States Surgical Corporation), 13 августа 1985 (13.08.85)	16

Форма PCT/ISA/210 (продолжение второго листа) (июль 1992)